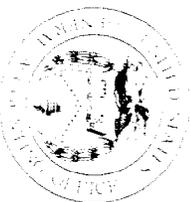


FRU review DOES NOT Assure Quality of Care Provided by Risk HMOs





United States
General Accounting Office
Washington, D.C. 20548

Human Resources Division

B-243093

March 13, 1991

The Honorable John Heinz
Ranking Minority Member
Special Committee on Aging
United States Senate

Dear Senator Heinz:

This report responds to your request concerning the extent to which the PRO review program provides reasonable assurance that Medicare beneficiaries enrolled in risk HMOs are receiving quality health care. It contains our analysis of the effectiveness of the PRO review of the (1) internal quality assurance programs at risk HMOs and (2) health care provided by these HMOs.

Comments on a draft of this report were obtained from the Secretary of Health and Human Services, Group Health Association of America, the American Managed Care and Review Association, and the American Medical Peer Review Association. Their comments have been incorporated in the final report as appropriate.

We are sending copies of this report to the Secretary of Health and Human Services, the Director of the Office of Management and Budget, the Administrator of the Health Care Financing Administration, interested congressional committees, and other interested parties.

This report was prepared under the direction of Janet L. Shikles, Director, Health Financing and Policy Issues, who may be reached on (202) 275-5451 if you have any questions. Other major contributors are listed in appendix VI.

Sincerely yours,

Lawrence H. Thompson
Assistant Comptroller General

Executive Summary

Purpose

About 1.2 million Medicare beneficiaries are enrolled in risk health maintenance organizations (HMOs). The HMOs contract with Medicare, agreeing to provide all necessary medical care for a set monthly payment. This payment system (called capitation) gives HMOs the incentive to be cost efficient and avoid unnecessary care. But it may also represent a potential threat to quality care by encouraging inappropriate reductions in services. To help protect Medicare enrollees from access and quality problems, peer review organizations (PROs) assess the care provided by risk HMOs.

Senator John Heinz, Ranking Minority Member of the Senate Special Committee on Aging, asked GAO to determine the extent to which the PRO review program provides reasonable assurance that Medicare beneficiaries enrolled in risk HMOs are receiving quality health care. Specifically, GAO evaluated the effectiveness of the PRO review of the (1) internal quality assurance programs at risk HMOs and (2) health care provided by these HMOs.

Background

The Health Care Financing Administration (HCFA), the federal agency responsible for managing Medicare, has to balance its efforts to contain program costs by increasing beneficiary enrollment in risk HMOs with its responsibility to ensure that beneficiaries receive quality health care.

To participate in Medicare, risk HMOs must meet certain federal requirements, such as having an internal quality assurance program (QAP) that is capable of identifying and correcting quality-of-care problems. HCFA reviews the HMOs to determine if they are structured to comply with these requirements.

To augment HCFA's HMO oversight activities, the Congress mandated that HCFA contract with PROs for an external medical assessment of the quality of care provided by risk HMOs on or after April 1, 1987. To make this assessment, the PROs review samples of HMO medical records related to both inpatient hospital and outpatient (ambulatory) care provided to Medicare enrollees. The PROs also have the medical capability to evaluate the effectiveness of HMO QAPs.

When the PRO/HMO review program began, 34 PROs were responsible for reviewing 152 risk HMOs.

Results in Brief

After more than 3 years of operation, the PRO review program has not provided the intended assurance that Medicare beneficiaries enrolled in risk HMOs are receiving quality health care.

The program's effectiveness has been impeded by a lack of strong central management from HCFA. First, rather than requiring PRO review of all HMO QAPs, HCFA made such reviews optional on the part of each HMO. Most risk HMOs have not subjected their QAPs to PRO review—in part because HCFA gave them no incentive to do so. HCFA, therefore, has no assurance that most HMOs are identifying and correcting quality-of-care problems. (See p. 16.)

Further, from the start, record-keeping inadequacies at most risk HMOs have jeopardized the PRO external review of HMO quality of care. HCFA has been aware of these problems but has been unsuccessful at solving them. The PROs have not had access to comprehensive HMO data from which to select their review samples. Thus, they have yet to conduct enough inpatient or ambulatory reviews to make a valid assessment of the quality of care at risk HMOs. (See p. 29.)

Finally, HCFA has lost the marginal benefit that could otherwise have been derived from PRO reviews that have been done because it has not incorporated the results into its own HMO oversight process.

GAO's Analysis

HCFA Has Not Effectively Used PROs to Assess HMO QAPs

Internal QAPs at risk HMOs—the first line of defense for protecting Medicare enrollees against substandard health care—are a logical starting point for federal oversight. HCFA considered using the PROs to evaluate the effectiveness of HMO QAPs, but made such evaluations optional on the part of the HMOs. HMOs had no incentive to subject their QAPs to PRO review because those with effective QAPs could be subject to as much PRO external review as those with ineffective QAPs. Only 57 of the 204 risk HMOs that have participated in Medicare have had their internal QAPs reviewed by the PROs. (See p. 19.)

Further, the PROs determined that 36 of the 57 QAPs reviewed could not demonstrate the capacity to identify and correct quality-of-care problems. For example, 10 did not have physicians or other health care

professionals review the HMOs' delivery of services. (See p. 21.) HCFA generally has not used the PRO findings in carrying out its HMO oversight activities, nor has it required the PROs to ensure that identified deficiencies were corrected. (See p. 22.)

PRO External Review Hampered by Data Problems

The PRO external review process can produce an unbiased, accurate assessment of the quality of care only if review samples are drawn randomly from a data base of all health care services provided to Medicare enrollees. However, the PROs were receiving information on only about 60 percent of Medicare enrollees receiving inpatient hospital care. (See p. 32.) Although HMOs are required by their contracts to comply with PRO review, the only punitive action available to HCFA in cases of noncompliance is contract termination. GAO believes that HCFA needs broader sanction options—such as monetary penalties—to ensure that HMOs provide the needed inpatient data to the PROs. HCFA has not sought such authority.

In addition, HCFA planned to have the PROs focus their reviews of ambulatory treatment on high-risk conditions and services. However, the lack of HMO centralized data needed to perform such reviews caused HCFA to abandon this approach, instead requiring PROs to sample from lists of enrollees. The start of PRO ambulatory review was delayed for over 2 years. (See p. 35.) HCFA has undertaken no effort to promote the development of a centralized data base needed for focused review. GAO believes that the current methodology for PRO ambulatory review may not be the most productive for identifying quality problems. HCFA should compare this approach to the potential costs and benefits associated with performing reviews that focus on high-risk conditions and services.

Data on PRO-identified problems are neither reported to HCFA on an HMO- or provider-specific basis nor routinely provided to the HCFA component responsible for monitoring risk HMOs. (See p. 36.)

Recommendation to the Congress

GAO is recommending that the Congress amend the Social Security Act to give HCFA explicit authority to impose appropriate remedies to help assure that risk HMOs comply in collecting and submitting the inpatient hospital information needed by the PROs to carry out their review responsibilities.

Recommendations to the Agency

GAO is recommending that the Secretary of Health and Human Services (HHS) strengthen the PRO review of risk HMOs by (1) making PRO review of QAPS mandatory (see p. 24), (2) identifying the most effective method for conducting external reviews of medical records, including encouraging HMOs to collect and provide data on ambulatory care (see p. 38), and (3) incorporating the results of PRO efforts into HCFA's HMO compliance monitoring process (see p. 38).

Agency Comments

HHS generally agreed with GAO's overall conclusion that the PRO review of HMOs has not achieved the intended results, and has proposed a new PRO review methodology that it believes will correct some of the problems identified. GAO has a number of concerns about HHS's proposal and does not believe it addresses the underlying problems that have hampered the PRO/HMO review program from the outset. (See p. 50.)

GAO also received and addressed comments from the Group Health Association of America (see p. 53), the American Managed Care and Review Association (see p. 63), and the American Medical Peer Review Association (see p. 69).

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Abbreviations

AMCRA	American Managed Care and Review Association
AMPRA	American Medical Peer Review Association
COBRA	Consolidated Omnibus Budget Reconciliation Act of 1985
GAO	General Accounting Office
GHAA	Group Health Association of America
HCFA	Health Care Financing Administration
HHS	Department of Health and Human Services
HMO	health maintenance organization
HSQB	Health Standards and Quality Bureau
IOM	Institute of Medicine
IPA	independent practice association
NCQA	National Committee for Quality Assurance
OBRA-86	Omnibus Budget Reconciliation Act of 1986
OMB	Office of Management and Budget
OPHC	Office of Prepaid Health Care
PHS	Public Health Service
PRO	peer review organization
QAP	quality assurance program
QRO	quality review organization
TEFRA	Tax Equity and Fiscal Responsibility Act of 1982

Introduction

In fiscal year 1990, about 1.2 million Medicare beneficiaries were enrolled in "risk" health maintenance organizations (HMOs), which provide care on a capitated payment basis. That is, Medicare pays the HMO a set monthly payment for each enrolled beneficiary and, in return, the HMO agrees to provide all necessary medical care. As a form of "managed care," risk HMOs represent an alternative to health care provided in the fee-for-service sector. Some HMOs offer Medicare enrollees a more comprehensive package of services than otherwise available under Medicare, often with little or no cost sharing by the enrollees. For Medicare, risk HMOs offer the potential for cost savings because the HMO payments are set at 95 percent of Medicare's estimate of the average cost it would have incurred for HMO enrollees had they remained in the fee-for-service sector.

The incentives of a fee-for-service payment system may encourage providing more services than necessary. In contrast, the incentives of a capitation payment system may encourage providing fewer services than necessary. Thus, federal oversight must ensure a balance between cost and quality—that HMO efforts to cut cost do not adversely affect access to and quality of care.

The Health Care Financing Administration (HCFA) is responsible for managing the Medicare program and, thus, for monitoring the quality of care provided to beneficiaries enrolled in risk HMOs. To augment HCFA's HMO oversight activities, the Congress mandated that, beginning in April 1987, peer review organizations (PROs) be used to assess the quality of HMO health care services. This report discusses the extent to which the PRO program has improved federal oversight of risk HMOs by providing assurance that Medicare enrollees are receiving quality health care.

The Medicare Program

Medicare, authorized by title XVIII of the Social Security Act, is a broad health insurance program available to most persons 65 years of age and older and to some disabled persons. Benefits are provided under two parts. Part A, hospital insurance, covers inpatient hospital, skilled nursing facility, home health, and hospice services. In fiscal year 1990, part A payments were expected to be \$64 billion for about 33 million beneficiaries. Part B, supplementary medical insurance, covers physician services and a broad range of other services furnished on an outpatient basis, such as laboratory and X-ray services, and medical equipment used in the home. In fiscal year 1990, part B was expected to pay \$44 billion.

HCFA, under the Department of Health and Human Services (HHS), contracts with insurance companies to process Medicare claims and make payments on behalf of the government. Contractors that pay hospitals and other institutional providers are referred to as fiscal intermediaries; contractors that pay doctors and other noninstitutional providers are called carriers.

HMOs and Medicare

Most Medicare beneficiaries receive their care in the fee-for-service sector of the health care system. In that sector, most inpatient hospital and hospice care is paid on the basis of prospectively determined rates, and skilled nursing facilities and home health agencies are paid on the basis of cost. Part B services are paid on a reasonable charge basis or, as in the case of laboratory and anesthesiology services, on a fee schedule basis.

Some Medicare beneficiaries are enrolled in HMOs. Under section 1876 of the Social Security Act, as amended by the Tax Equity and Fiscal Responsibility Act of 1982 (P.L. 97-248, Sept. 3, 1982) (TEFRA), HMOs that enroll Medicare beneficiaries may be paid in one of two ways for all covered services. First, they may be paid for the actual cost of caring for the Medicare beneficiaries enrolled in the plan. The payment is estimated in advance on the basis of the HMO's experience, and adjusted retroactively to reflect actual allowable costs.

Alternatively, if the HMO meets certain conditions, it can enter into a risk contract with Medicare. TEFRA modified Medicare's authority to enter into risk contracts with HMOs and revised the reimbursement provisions for such contracts. Under these TEFRA risk contracts, HMOs agree to provide all covered health care services to enrolled Medicare beneficiaries in return for a fixed payment per enrollee. The payment is set at 95 percent of Medicare's estimate of the average cost it would have incurred for HMO enrollees had they remained in the fee-for-service sector. This estimate is referred to as the adjusted average per capita cost. Within certain limits, the HMO can profit if its cost of providing services is less than the predetermined amount, but risks a loss should its costs be higher.

There are four common organizational structures for HMOs:

- Staff HMOs provide medical services at central facilities through physicians who are employed by the HMO.

- Group practice HMOs contract with one independent single—or multiple—specialty group practice to provide services. The physicians in the group share facilities, equipment, medical records, and support staff, but are not employed by the HMO.
- Individual practice association (IPA) HMOs contract with physicians in the community to provide medical services to HMO members through their regular practices. Such an HMO may contract with physicians who are members of an association (a network IPA) or directly with individual physicians (a direct contract IPA).
- Network HMOs contract on a capitation basis with more than one independent group practice to provide health services. Some HMOs are “mixed networks” because their structure contains some mix of group, IPA, and staff model practices.

The IPA model HMO has been the most common type to participate in Medicare. Specifically, of the 204 HMOs that had contracts with HCFA through March 1989, 129 were IPA models.

In February 1985, as part of an effort to contain the growth of Medicare costs and after a 3-year demonstration period, HHS began a nationwide program to increase enrollment of Medicare beneficiaries in risk HMOs.¹ At that time, HHS published regulations implementing the risk-contracting provisions of TEFRA.

The first TEFRA risk contracts for other-than-demonstration projects were executed in April 1985. Since then, the number of risk HMOs participating in Medicare, as well as the number of program beneficiaries enrolled, has grown. Table 1.1 shows the number of risk HMOs, the number of Medicare enrollees, and the annual Medicare payments to such HMOs for the period April 1985 through fiscal year 1990.

¹In addition to HMOs, Medicare also contracts with competitive medical plans. These are providers that operate like HMOs in that they are reimbursed on a capitation basis. They are subject to essentially the same regulatory requirements as HMOs except that they are permitted more flexibility in how they set their commercial premium rates and the services they offer commercial members. As of September 30, 1990, 15 competitive medical plans were participating in Medicare. Our use of the term HMO in this report also refers to these plans.

Table 1.1: Participating Risk HMOs, Beneficiaries Enrolled, and Medicare Payments (Fiscal Years 1985-90)

Dollars in billions

Fiscal year	Number of HMOs with risk contracts ^a	Number of Medicare enrollees ^a	Medicare payments to HMOs
1985 ^b	68	383,480	\$.4
1986	143	772,488	1.4
1987	158	981,068	2.2
1988	155	1,047,423	2.8
1989	131	1,113,939	3.4
1990	96	1,238,479	4.2

^aAs of the end of the fiscal year.

^bBeginning April 1985.

In addition to the potential cost containment benefits to Medicare, HMOs also offer a number of advantages to program beneficiaries. These include reduced out-of-pocket costs, coordinated care, and a more comprehensive package of benefits than normally offered through Medicare. For these reasons, the current administration has given high priority to further expanding the use of HMOs and other forms of managed care in the Medicare program.

Federal Oversight of Quality of Care Provided to Medicare HMO Enrollees

The capitated payment method gives risk HMOs a financial incentive to control the use of services and assure that only necessary care is provided. In turn, HMOs often give their participating physicians financial incentives to hold down the cost of the care these physicians provide or prescribe. Many are concerned, however, that the incentives given to the participating physicians pose a potential threat to the quality of care by encouraging inappropriate reductions in service. In a December 1988 report, we argued that the more risk transferred to physicians and the more closely financial incentives are linked to decisions about individual patients, the greater the potential threat to quality.² The Congress subsequently, in the Omnibus Budget Reconciliation Act of 1990 (P.L. 101-508, Nov. 21, 1990), took action to regulate incentive payments to physicians.

Both the Public Health Service (PHS) Act and TEFRA provide safeguards to mitigate this potential threat to quality of care. As a condition of entering into a TEFRA risk-based contract with Medicare, an HMO must

²Medicare: Physician Incentive Payments by Prepaid Health Plans Could Lower Quality of Care (GAO/HRD-88-28, Dec. 12, 1988).

demonstrate an ability to comply with PHS Act requirements pertaining to its management, market area, and internal quality assurance mechanisms. The HMO must also meet certain financial solvency requirements to protect enrollees against the risk of its going bankrupt. For instance, the HMO must have (1) assets greater than liabilities, (2) sufficient cash flow and adequate liquidity to meet its obligations as they become due, and (3) a net operating surplus.

Further, the Social Security Act requires each federally qualified HMO participating in Medicare to

- have a fiscally sound operation and a plan for handling insolvency to protect its members against the risk of its going bankrupt,
- have enrolled at least 5,000 members (rural HMOs must have at least 1,500), and
- limit the number of Medicare and Medicaid enrollees to 50 percent of the total membership to help assure quality of care (on the premise that an HMO's ability to attract substantial commercial membership is an indication that the quality of care meets community standards).

HCFA is responsible for assuring the quality of care provided to Medicare HMO enrollees and, until April 1987, performed all oversight activities using its central and regional office resources. HCFA's Office of Prepaid Health Care (OPHC) has overall responsibility for monitoring contracts with Medicare risk HMOs.

Two OPHC units share this responsibility. The Office of Qualification reviews applications for Medicare risk contracts to ensure that HMOs meet applicable statutory and regulatory requirements. The Office of Compliance is responsible for ensuring that federally qualified HMOs continue to meet these requirements and other contractual provisions. The Office of Compliance monitors HMOs by

- reviewing HMO financial and utilization data,
- conducting periodic on-site reviews, and
- tracking and investigating beneficiary complaints.

Long-standing compliance problems at International Medical Centers, Inc.—a south Florida HMO that became insolvent and was placed in receivership by the state in May 1987—raised serious questions about the effectiveness of HCFA's oversight of the HMO program. In response to a congressional request, we evaluated several aspects of HCFA's HMO

monitoring program. In August 1988 we reported that (1) HCFA had relatively limited data with which to monitor HMOs' quality of care, (2) HCFA's staffing for compliance monitoring had not kept pace with HMO growth, and (3) HCFA did not always act quickly and effectively to resolve problems identified through its HMO oversight activities.³

However, we also reported that during our study, HCFA was in the first year of contracting with PROs to evaluate the quality of care provided to Medicare HMO enrollees. We stated that, although it was too soon then to fully assess the new program, the PRO review of HMO medical records offered the potential to enhance HCFA's oversight activities.

PRO Review of HMO Quality of Care

The PRO program for Medicare fee-for-service health care was established by TEFRA. Under contract with HHS, PROs began reviewing the necessity, appropriateness, and quality of inpatient hospital services in 1984.⁴ HCFA's Health Standards and Quality Bureau (HSQB) is responsible for negotiating and monitoring the PRO contracts.

Partly because of concerns about possible incentives for underutilization of services (providing fewer medical services than necessary), the Congress, in the Consolidated Omnibus Budget Reconciliation Act of 1985 (P.L. 99-272, Apr. 7, 1986) (COBRA), required PRO review of inpatient and outpatient services provided to Medicare HMO enrollees on or after January 1, 1987.

The Omnibus Budget Reconciliation Act of 1986 (P.L. 99-509, Oct. 21, 1986) (OBRA-86) amended the COBRA provision permitting the Secretary to contract with entities other than PROs for the HMO reviews. These organizations were called quality review organizations (QROs).⁵ OBRA-86 limited contracts with QROs to no more than half of the states, and no more than half of the total population of Medicare beneficiaries enrolled in risk HMOs. In addition, OBRA-86 changed the effective date of the mandated PRO review of HMO services to April 1, 1987.

³Medicare: Experience Shows Ways to Improve Oversight of Health Maintenance Organizations (GAO/HRD-88-73, Aug. 17, 1988).

⁴TEFRA replaced the Professional Standards Review Organization program with the Quality Peer Review Organization—the PRO program.

⁵QROs perform the same functions as PROs, except that they do not have contracts with HCFA to review inpatient hospital services under the fee-for-service program. In chapters 2 and 3, we use the term PRO to refer to both PROs and QROs.

In April 1988, when we started our work, HCFA had contracts with 29 PROs and 1 QRO to review HMO quality of care. The QRO left the program, and as of September 30, 1990, there were 30 PROs participating.

Objectives, Scope, and Methodology

In a letter dated April 25, 1988, Senator John Heinz, Ranking Minority Member of the Senate Special Committee on Aging, asked us to review HCFA's management of the PRO review of risk HMOs and the program's effectiveness in assuring the quality of care provided to Medicare enrollees. Through later discussions with the committee staff, we agreed to review

- the PRO review of the internal quality assurance programs at risk HMOs and
- the PRO external review of health care provided by risk HMOs.

We performed our work at HCFA's headquarters offices in Washington, D.C., and Baltimore and at its regional offices in Atlanta, Chicago, and San Francisco. At these offices, we interviewed officials and reviewed documents on HCFA's oversight of the PRO and HMO programs.

We also visited five PROs and one QRO. These six organizations were responsible for reviewing 42 of the 152 risk HMOs that had contracts with HCFA when the PRO/HMO review program began in April 1987. At the PROs, we met with administrators and medical personnel and reviewed documentation related to the PROs' role in reviewing risk HMOs.

In addition, we visited 10 of the 42 risk HMOs. These 10 HMOs served about 39 percent of Medicare beneficiaries enrolled in risk HMOs on April 1, 1987. At the HMOs, we met with officials and reviewed records to gain an understanding of their quality assurance methods, discussed HCFA's formulation and implementation of the PRO review program and its effect on HMOs, determined how the HMOs correct PRO-identified quality problems, and reviewed HMO policies and procedures for handling beneficiary complaints. The names and locations of the PROs and HMOs included in our study are listed in appendix I.

We also discussed the issues presented in this report with the American Medical Peer Review Association (AMPRA—the PRO trade association); the Group Health Association of America (GHAA) and the American Managed Care and Review Association (AMCRA), both representatives of the HMO industry; and the American Association of Retired Persons. Finally,

we reviewed numerous published studies on PROs and HMOs and, where possible, discussed them with their authors.

We performed our work between April 1988 and June 1990 in accordance with generally accepted government auditing standards.

HCFA Has Not Effectively Used PROs to Assess HMO Quality Assurance Programs

Health care providers have the primary responsibility for assuring quality. For institutional and group providers—such as hospitals, home health agencies, and HMOs—an internal quality assurance program (QAP) can be instrumental in carrying out this responsibility. It is particularly important that risk HMOs have an effective internal QAP because the Medicare capitation payment system could provide incentives to inappropriately reduce services. Thus, a comprehensive program for federal oversight of quality of care provided to Medicare HMO enrollees should begin with an evaluation or validation of the HMOs' internal QAPs.

The PROs give HCFA the potential for a substantive medical evaluation of the effectiveness of HMO internal QAPs. HCFA, however, has not fully benefited from this opportunity because it made the PRO review of QAPs optional on the part of the HMOs. Only 57 of the 204 risk HMOs that have participated in the Medicare program have had their internal QAP reviewed by the PROs.

Further, the PROs determined that 36 of the 57 QAPs reviewed were unable to demonstrate the capability to identify and correct quality-of-care problems. HCFA generally has not used these results in its oversight activities and continues to rely on the deficient HMO QAPs to ensure that serious quality-of-care problems are corrected. HCFA has no plans to have the PROs review all HMO internal QAPs or to reevaluate the QAPs determined to be ineffective.

Effective Internal QAPs at Risk HMOs Are Essential

An internal QAP includes the HMO's processes and procedures established to detect instances of inadequate medical treatment provided to its enrollees and to correct the problems causing the substandard care. As an internal control mechanism, a properly implemented QAP represents the first line of defense against quality and access problems.

The Congress recognized the importance of HMO QAPs in protecting Medicare enrollees from substandard health care. As a condition for participating in Medicare, HMOs are required by law to have an ongoing QAP which assures that the HMO is routinely evaluating its health care delivery system to make improvements. Implementing regulations require each HMO to have a QAP that (1) stresses health outcomes, (2) provides review by physicians and other health professionals of the HMO's delivery of services, (3) uses systematic collection of data of treatment results and provides feedback to the practitioners to institute needed change, and (4) includes written procedures for taking needed remedial action.

Studies by Mathematica Policy Research, the Institute of Medicine (IOM), and the Physician Payment Review Commission also highlight the importance of effective QAPS.¹ Finally, HMOs also recognize the value of QAPS. The national trade association for the managed health care industry, AMCRA, noted at its 1990 health policy conference that “quality assurance is one of the most vital areas of HMO endeavor today.”

HCFA Does Not Have a Comprehensive Assessment of the Effectiveness of Most HMO QAPs

Because of their importance in protecting Medicare enrollees from substandard care, internal QAPS are a logical starting point for federal oversight of quality of care at risk HMOs. The recent IOM study concluded that a key operational feature of the government’s program to assure quality in Medicare should be an evaluation of provider internal QAPS. The IOM study suggests that the level of external monitoring of quality of care should be related to the effectiveness of the provider’s internal program. Providers with effective programs could be rewarded by having less external monitoring and review.

HCFA, however, has not adopted this concept and does not know how effective most HMO QAPS are at identifying and correcting quality problems. HCFA’s own reviews of HMOs focus on the structural aspects of QAPS—that is, they attempt to validate the existence of a QAP rather than evaluate its effectiveness. HCFA could have required PROs to review the effectiveness of all QAPS as a way of complementing its own structural reviews, but made such evaluations optional. Most HMOs have chosen not to subject their QAP to PRO review.

HCFA’s Reviews of HMO QAPs Focus on Structure Rather Than Effectiveness

Before an HMO may participate in Medicare, HCFA conducts a formal review to determine if the HMO meets certain federal requirements. During this “certification” review, HCFA’s Office of Qualification looks at several indicators of the HMO’s ability to provide quality treatment to Medicare enrollees, including documentation describing its financial condition, its marketing projections, the qualifications of its management staff, and its management information systems. Generally, HCFA does not visit the HMO as part of the certification review, but instead reviews its plans and proposed procedures.

¹The Structure of Quality Assurance Programs in HMOs and CMPs Enrolling Medicare Beneficiaries. Report submitted to HCFA by Mathematica Policy Research, Inc., under contract No. 500-83-0047, February 1987. Physician Payment Review Commission, Annual Report to Congress, 1989. Institute of Medicine, Medicare: A Strategy for Quality Assurance, 1990.

As part of the certification review, HCFA analyzes documents describing the HMO's proposed QAP. Basically, HCFA attempts to determine that the HMO has a written quality assurance plan, a functioning quality assurance committee, and physician supervision of quality assurance activities. During this process, HCFA is limited to appraising documents that describe the QAP, but cannot measure its effectiveness because the HMO has not yet begun to treat Medicare enrollees. In effect, HCFA determines if the HMO has designed a QAP that—if properly implemented—would ensure that it delivers high-quality service.

After an HMO is accepted into Medicare, HCFA performs biannual reviews to ensure that the HMO remains in compliance with federal requirements. During these on-site evaluations, HCFA reviews the status of the same elements that it reviewed during the certification review. In addition, because the HMO has been treating Medicare enrollees, HCFA reviewers can look for indicators that the QAP is operational. This effort may include discussions with HMO officials and a review of documents to determine, for example, if the HMO has (1) a committee that meets regularly to discuss quality issues, (2) a plan for selecting and reviewing patient files, (3) a board of directors that routinely receives reports on quality issues, and (4) a system for following up and resolving beneficiary complaints.

The compliance reviews—like the certification reviews—help HCFA determine if the QAP meets federal structural requirements, but they do not determine whether the QAP is performing the way supporting documents and HMO employees may indicate. An evaluation of the effectiveness of QAPs would require medical judgments that are beyond the capability of the HCFA review teams, which do not include physicians or nurses.

HCFA Made PRO Review of HMO QAPs Optional

The PROs have the medical capability to evaluate the effectiveness of HMO QAPs, and HCFA initially planned to have them evaluate the QAP of each risk HMO. Ultimately, however, HCFA decided to make the PRO review of HMO QAPs optional.

OBRA-86 required peer review of HMO services beginning April 1, 1987. As part of the budget negotiations to fund this new program, the Office of Management and Budget (OMB) recommended that the starting point for the PRO oversight of HMOs should be a PRO evaluation of the HMO QAP. OMB believed that HMOs with a QAP that could demonstrate the capacity to

identify and correct quality problems should be subject to a lower level of subsequent PRO review of medical records.

HCFA incorporated OMB's suggestion into the request for proposal that was sent to prospective PROs in March 1987. In that document, HCFA indicated that each PRO would be required to "perform an initial analysis of each HMO ... to determine the appropriate level of review to be performed by the contractor." As part of this initial analysis, the PRO contracts required that the PRO review medical records that had been previously reviewed as part of the QAP.

HMOs with an effective QAP would be placed on the "limited" PRO review plan, while those with a QAP that could not demonstrate the ability to identify and correct quality problems would be placed on the "basic" level of PRO review. Both the limited and basic plans would include the same categories of medical records to be reviewed (see p. 30), but the basic review plan specified larger sample sizes for some of the review categories.

HCFA apparently believed that most of the HMOs participating in Medicare at that time did not have a QAP capable of identifying and correcting quality problems. The HCFA Administrator expressed this belief in a June 1987 letter to Senator John Heinz, stating that "very few plans will qualify for limited review—our working estimate is 10 percent—while the remaining will be subject to the basic plan..."

Despite these reservations about the effectiveness of the HMO QAPS, HCFA altered its plans and made the PRO review of QAPS optional on the part of each HMO. HMOs that chose not to subject their QAP to PRO review were placed automatically on the basic level of PRO external review, along with HMOs reviewed and found to have an ineffective QAP. HCFA officials were unable to state specifically why this change was made. An official involved in developing the PRO contracts told us initially that he believed the change came about as a result of discussions between HCFA and representatives of the HMO industry. He later said, however, that the change was made "somewhere in HCFA's internal review process," but he was unable to provide us with any supporting documentation.

Given the option of PRO review of their QAPS, only 57 of the 204 risk HMOs that have participated in the Medicare program have volunteered for such reviews. There are a number of reasons why most HMOs have chosen not to have the PROs review their QAPS. Some were simply opposed to any outside scrutiny. Others questioned the PROs' ability to

objectively evaluate their internal programs. Still others may not have had an operating QAP in place, or perhaps lacked confidence in the effectiveness of their QAP (see p. 21).

In our opinion, a major reason for HMOs not subjecting their QAP to PRO review was that HCFA gave them no incentive to do so. As discussed above, HMOs found to have an effective QAP would later have a sample of their medical records reviewed by the PROs under the limited review plan. In addition, HCFA required that the PROs continue to monitor the effective QAPs by reviewing quarterly subsamples of medical records that had been reviewed previously by these QAPs. There was no similar monitoring requirement for HMOs on the basic review plan.

Because of the additional medical records that the PRO reviews as part of the quarterly subsamples, HMOs with effective QAPs could be subject to as much subsequent PRO review as HMOs whose QAPs were not reviewed, or reviewed but determined to be ineffective. For this reason, the executive director of FHP, a California risk HMO, told us that attaining limited review, in his opinion, was actually a “punishment” rather than an advantage to the HMO.

When we completed our work, HCFA had no plans to make PRO reviews of QAPs mandatory. Thus, HCFA does not have—nor will it have—a true assessment of the effectiveness of the internal QAPs for most of the risk HMOs treating Medicare enrollees.

Like OMB and IOM, we believe that federal oversight of HMO quality should begin with a comprehensive assessment of the HMO QAPs. This view is also shared, to some extent, by the trade association for the managed care industry. One of the recommendations made by AMCRA’s Medicare Policy Task Force in April 1990 was that “HCFA should utilize the PROs to review externally and to validate and/or make recommendations for improvement in the adequacy of an HMO’s active internal quality assurance program...” The task force favored eliminating any further PRO review for HMOs that demonstrate that their internal QAP is adequate.

We agree that HCFA should use the PROs to validate the HMO QAPs. Although we do not support eliminating the PRO review of HMO medical records, the burden of PRO review on HMOs—and the cost to the government—could be reduced if the level of subsequent PRO review was set to reflect the results of the QAP review. The primary benefit, however, of validating the effectiveness of the internal QAPs would be to provide

greater assurance that Medicare beneficiaries enrolled in risk HMOs are receiving quality health care.

Some HMO QAPs Do Not Have the Capacity to Identify and Correct Quality Problems

The PROs determined that 36 of the 57 QAPs reviewed could not demonstrate the capacity to identify and correct quality-of-care problems.

We reviewed documentation related to the PROs' assessment of 20 of the 36 QAPs, which were based, in part, upon PRO review of medical records that had previously been reviewed as part of the QAP. The results of the PRO analyses suggest that these QAPs had serious weaknesses that violated federal regulations. For example, the PROs found that 10 QAPs did not have physicians or other health professionals review the HMO's delivery of services, 4 lacked a data collection system capable of collecting and interpreting information on treatment outcomes, and 9 lacked written procedures identifying corrective actions to remedy health care problems.

HCFA provided only general guidance to PROs related to the assessment of the HMO QAPs, and we noted that the PROs used different review guidelines and scoring methods in evaluating the QAPs. In general, however, the review criteria were based directly on federal regulations. Many of the criteria, in fact, were identical to those that HCFA uses in its biannual reviews.

Further, the results of the PRO evaluations of the 57 HMO QAPs were consistent with findings of an earlier Mathematica study (see p. 17). In June 1987 testimony given before the House Select Committee on Aging, the project director summarized the study findings, stating "what some HMOs say they have in place as quality assurance programs aren't actually operating effectively, and in some cases aren't operating at all."²

HMOs Not Required to Correct Deficient QAPs

Neither the PROs nor HCFA has acted to ensure that the HMOs correct the PRO-identified deficiencies in their QAPs. The PROs have no contractual requirement to follow up on these deficiencies to ensure that they are corrected, and PRO officials said they do not monitor HMO efforts to improve their QAPs because they lack the authority to enforce corrective action. None of the 36 HMOs with a deficient QAP had requested the PRO to reevaluate its program.

²Maintaining Medicare HMOs: Problems, Protections and Prospects, House Committee Publication No. 100-627, June 11, 1987, p. 96.

As discussed on page 18, HCFA performs biannual reviews of HMO QAPs to ensure that they continue to comply with regulatory requirements. HCFA can take a variety of actions—including initiating termination procedures—against HMOs found to be in continuing noncompliance with regulations. Officials from the office responsible for HMO compliance monitoring told us that they considered the results of the PRO QAP reviews but generally have not required the HMOs to take corrective action on the PRO-identified deficiencies. They said that they followed up on only 1 of the 36 deficient QAPs, adding that they were reluctant to accept the PRO findings because of the lack of uniformity in the process the PROs used in assessing the QAPs.

HCFA Continues to Rely on Deficient QAPs to Correct Serious Quality Problems

One of the critical functions performed by HMO internal QAPs is ensuring that quality-of-care problems are corrected. We are concerned, therefore, that HCFA has not used the PROs to evaluate how well most HMO QAPs are performing this important function. It is even more disturbing, however, to find that those QAPs that have been reviewed by the PROs and determined to be inadequate are still relied upon to ensure that serious quality problems are corrected.

A risk HMO is required to develop a corrective action plan when the PRO identifies patterns of quality problems (see p. 36), when the number of PRO-identified problems exceeds established thresholds, and when the PRO determines that an individual quality problem is “gross and flagrant.” HMOs are also expected to “take appropriate corrective action” for each confirmed quality problem that, while not gross and flagrant, is still considered serious—that is, that the PRO classified as a “severity II or severity III” quality problem.³

Between April 1987 and March 1989, PROs identified 90 serious quality problems at 4 of the 10 HMOs in our review (see p. 14). (They found no serious quality problems at the other 6 HMOs.) To examine the types of corrective actions proposed by these HMOs, we requested from both the HMO and the PRO all documentation related to the 90 PRO-identified quality problems. We received and reviewed documentation for 62 of the 90 cases; neither the HMO nor the PRO could provide documentation in the other 28 cases.

³A severity II problem is defined as one with the potential for significant adverse effects on the patient, while a severity III problem is one that has resulted in significant adverse effects on the patient. “Significant adverse effects” can range from unnecessarily prolonged treatment to disability or death.

Our review of the documented cases showed that HMOs, in their written response to the PROs, often proposed referring the PRO-identified quality problems to their internal QAPs for corrective action—even though all four of the QAPs in question had been found by the PROs to be ineffective in identifying and correcting quality problems.

In one case that we reviewed, for example, the PRO determined that an HMO physician had provided substandard health care to an 89-year-old Medicare enrollee. The physician diagnosed the enrollee as suffering from a lack of oxygen in his blood 14 days after being discharged from a hospital following ankle surgery. The elderly enrollee was not readmitted to the hospital until 2 days after the diagnosis was made, and died on the day of admission.

The PRO reviewed the medical records related to this case and concluded that upon making the diagnosis, the HMO physician should have either hospitalized the enrollee or placed him on anticoagulants. This conclusion was based on the enrollee's susceptibility to post-operative pulmonary embolisms (obstruction of the blood vessels in the lungs) due to his advanced age. The HMO's senior medical director reviewed the medical records and agreed with the PRO. He concluded that, while the outcome may have been the same, the physician's actions were conservative given the circumstances of this case and that the documentation was insufficient to support the physician's decision. The medical director indicated that the case would be referred to the HMO's QAP for corrective action.

We do not know what, if any, action the HMO took in this case because the PRO contracts do not require them to monitor the implementation of corrective action plans for severity II and III quality problems, and we found no evidence that they are doing so.

In summary, we believe that relying on an HMO's QAP to correct health care problems when it has not demonstrated the ability to do so represents a serious quality control weakness. In our opinion, neither the PRO nor HCFA has reasonable assurance that serious quality-of-care problems are being corrected where this condition exists.

Conclusions

Because the incentives of a capitated payment system could result in the inappropriate reduction of services, effective internal QAPs at risk HMOs play a key role in ensuring that Medicare enrollees receive quality

health care. Yet HCFA lacks a comprehensive assessment of the effectiveness of the QAPs at most risk HMOs currently treating Medicare beneficiaries.

As the agency responsible for oversight of the care provided to Medicare HMO enrollees, HCFA could have used the medical expertise of the PROs to review QAPs in a way that complemented its own structural reviews of the HMO programs. Instead, HCFA

- made PRO review of HMO QAPs optional and gave HMOs little incentive to volunteer for such a review,
- gave the PROs only general guidance on how to conduct the QAP reviews,
- has not required that the PROs monitor deficient QAPs to ensure that identified shortcomings are corrected, and
- generally has not used the information about the PRO-identified QAP deficiencies in its HMO compliance reviews.

We believe that HCFA's oversight of the quality of care provided by risk HMOs should begin with a substantive evaluation of the internal QAP of each risk HMO. Viewed as part of a comprehensive strategy, the PRO review of QAPs could help determine the appropriate level of subsequent external review that may be required. This approach could help reduce the administrative burden on HMOs—as well as the cost to the government—by reducing the number of medical records reviewed at HMOs with effective QAPs. More importantly, it would also reduce the risk to Medicare beneficiaries enrolled in HMOs.

Recommendations to the Secretary of HHS

We recommend that the Secretary direct the Administrator of HCFA to:

1. Amend the HMO and PRO contracts, at the earliest opportunity, to make mandatory the PRO review of QAPs of all risk HMOs participating in the Medicare program. This requirement should include provisions for HMO corrective action and PRO follow-up where the HMO QAP cannot demonstrate the capacity to identify and correct quality-of-care problems and periodic PRO monitoring of those QAPs found to be effective.
2. In cooperation with the PROs and HMOs, develop uniform review guidelines to be used by the PROs in assessing the effectiveness of HMO QAPs.
3. Review the requirements for the PRO external quality review of HMO medical records and make adjustments to ensure that review levels are commensurate with the effectiveness of the QAPs. That is, HMOs with

QAPS that can demonstrate the capacity to identify and correct quality problems should be subject to lower levels of external PRO review.

Agency and Association Comments and Our Evaluation

HHS HHS disagreed with our recommendation to make PRO review of HMO QAPS mandatory. It stated that legislation establishing PRO review did not require PROs to do such reviews. HHS also contended that we did not consider the fact that QAPS are reviewed as part of HCFA's qualification and biannual certification reviews, and that PRO reviews of QAPS would be redundant. (See app. II.)

We agree that legislation did not require PRO review of HMO QAPS. However, we believe that there were—and still are—good reasons why HCFA should have adhered to its original plan of having PROs review all QAPS. The Congress emphasized the importance of QAPS by requiring each HMO that joined Medicare to establish a QAP capable of identifying and correcting quality problems (see p. 16). Because of their experience and expertise in assessing the delivery of medical services, the PROs offered HCFA the potential for performing a substantive medical evaluation of the performance of each QAP.

Further, as OMB suggested, the PRO review of QAPS was a good starting point for establishing the subsequent level of PRO review of risk HMOs. Finally, the HCFA Administrator, at the time PRO reviews began, expressed reservations about the ability of most QAPS to identify and correct quality problems and indicated to the Ranking Minority Member, Senate Special Committee on Aging, that PROs would review all risk HMO QAPS.

We disagree with HHS's contention that we have not considered the fact that HCFA reviews QAPS as part of its qualification and compliance reviews and that further PRO review would be redundant. HCFA's reviews are discussed on pages 12 and 17. However, as discussed on page 18, there is an important distinction between HCFA and PRO reviews of QAPS. HCFA's reviews focus on the structural aspects of QAPS—that is, they attempt to validate the existence of a QAP rather than its effectiveness.

PRO reviews can determine if a QAP is effective, because they include a reevaluation of medical records that were previously reviewed as part of the QAP.

Concerning our recommendation that HCFA develop uniform review guidelines for the PROs to assess QAPS, HHS indicated that HCFA has such guidelines. As we stated on page 21, HCFA provided only general guidance to the PROs on how to conduct QAP reviews when the PRO program began. During our evaluation, we found no evidence that standard guidelines had been developed. We also contacted HCFA officials responsible for PRO reviews after receiving HHS's comments and they confirmed that uniform PRO review guidelines do not exist. It appears that the HHS response is referring to guidelines used by HCFA in performing its QAP reviews, rather than to guidelines used by the PROs in reviewing QAPS.

Regarding our recommendation that HCFA ensure that PRO external review levels are commensurate with QAP effectiveness (as determined by PRO review), HHS responded that this might be accomplished in the long term, but cannot be implemented now because of a lack of uniform outcome data needed to assess the QAPS.

We disagree with HHS that the lack of uniform outcome data would prevent the PROs, given their medical expertise, from accurately assessing QAPS. This apparent shortcoming does not prevent HCFA from performing its own evaluation of QAPS which it characterizes as productive. Thus, we continue to believe that PRO external review levels should be made commensurate with QAP effectiveness as determined by PRO review.

GHAA

GHAA, the trade association representing HMOs, agreed with our conclusion that all QAPS should be subjected to external review, but questioned whether the PROs have the experience and expertise necessary to perform the reviews. GHAA suggested that alternative review organizations should be considered and discussed its reasoning for pursuing these alternatives. For GHAA's comments and our response, see appendix III.

AMCRA

AMCRA, the national trade association for the managed health care industry, disagreed with our conclusions and recommendations concerning the PRO review of QAPS at risk HMOs. AMCRA stated that the report suggests that "the only possible reason for the failure" of PRO review of QAPS is "some inadequacy or failure" on the part of the QAPS at risk

HMOs. AMCRA believes that it is the "PRO's lack of methodological expertise and competence" in assessing the effectiveness of the internal QAPs that is responsible for the "failure of the PRO review system to achieve what was intended." AMCRA believes that this is the primary reason for the reluctance of (1) HCFA to mandate PRO review of QAPs, and (2) risk HMOs to voluntarily undergo QAP review. (See app. IV.)

AMCRA also stated that we do not discuss what criteria HCFA or the PROs have developed for assessing risk HMO QAPs, nor how the PROs evaluated the information they received from the QAPs reviewed. AMCRA believes that the lack of guidance on technical evaluative issues from HCFA also contributed to the failure of the PRO review of QAPs. AMCRA suggests that the solution is for the PROs to better understand managed care delivery mechanisms so that appropriate review criteria can be developed and applied.

We question AMCRA's interpretation of our conclusions as to why the PRO review of risk HMO QAPs was unsuccessful. As stated on pages 16 and 24, the major problems we identified were that HCFA (1) made PRO review of HMO QAPs optional, (2) provided the PROs with only general guidance on how to conduct QAP reviews, (3) has not required that the PROs monitor deficient QAPs to ensure that identified shortcomings are corrected, and (4) generally has not used the information about the PRO-identified deficiencies in its compliance reviews. The report suggests that one of the reasons some risk HMOs did not subject their QAPs to PRO review may have been a lack of confidence in the effectiveness of their QAPs (see p. 20). However, this was just one of several reasons cited and, as stated on page 20, not the primary one.

Further, AMCRA provided no evidence to support its assertion that PRO review of HMO QAPs failed because PROs lack the competency to perform such reviews. Finally, AMCRA's statement that the report does not discuss (1) HCFA guidance provided to the PROs for doing QAP reviews and (2) the PRO method for evaluating QAPs, is inaccurate. The report states on page 21 that HCFA provided only general guidance to PROs related to the assessment of the HMO QAPs, and that the PROs used different review guidelines and scoring methods in evaluating the effectiveness of the QAPs. Accordingly, one of our recommendations is that HCFA develop, in cooperation with the PROs and HMOs, uniform review guidelines to be used by the PROs in assessing the effectiveness of HMO QAPs. Thus, while AMCRA stated that it disagrees with our recommendation, it appears that its "solution" to the problem is similar to ours.

AMPRA

AMPRA, representing PROs, said that it applauds our study and stands ready to work with appropriate parties to develop a quality review program that can provide needed assurances to beneficiaries participating in Medicare risk HMOs. AMPRA's complete response is in appendix V.

PRO External Review Does Not Assure the Quality of Care Provided by Risk HMOs

While effective internal quality assurance programs are essential for assuring the quality of care provided by risk HMOs, the Congress believed that external peer review was also necessary to protect Medicare HMO enrollees from access and quality problems. The PRO external reviews, which began in 1987, were intended to strengthen HCFA's oversight by providing a systematic medical evaluation of the care provided by risk HMOs. This program's success, however, was jeopardized from the outset because the PROs have not had access to comprehensive HMO data from which to draw valid review samples.

The PROs' efforts to review inpatient hospital care provided to Medicare enrollees have been limited because HCFA has not acted to ensure that HMOs provide the needed information about hospitalized enrollees. Likewise, the lack of centralized data on ambulatory patients at most HMOs caused HCFA to significantly alter its plans for focusing PRO reviews on high-risk medical conditions and treatment, instead requiring PROs to sample from lists of enrollees. This delayed the start of the PRO review of ambulatory care for almost 2 years. HCFA has no efforts underway, or planned, to promote the development of comprehensive HMO data needed for focused ambulatory review.

Because of these data problems, the PROs have not reviewed enough medical records to make a valid assessment of the quality of care provided to HMO enrollees. Further, HCFA has not incorporated into its HMO compliance monitoring process the results of completed PRO reviews. Thus, after more than 3 years of operation, the PRO external review program has not provided the intended assurance that Medicare HMO enrollees are receiving quality health care and has done little to enhance HCFA's federal oversight of risk HMOs.

PRO External Review of Risk HMOs

To ensure that risk HMOs provide Medicare enrollees with treatment that meets professionally recognized standards, the Congress required PRO review of the quality of health care provided by risk HMOs. In 1987, HCFA began amending the contracts of the PROs that were already performing utilization and quality reviews of inpatient hospital care provided under the fee-for-service system. By January 1988, HCFA had revised the scope of work in 34 of the 54 PRO contracts to require the retrospective review of health care services provided on or after April 1, 1987, by participating risk HMOs.

The PRO contracts required sample reviews from six "categories of review"—five related to inpatient hospital services and one related to

ambulatory care.¹ For example, to assess the quality of and access to inpatient hospital care provided to Medicare HMO enrollees, the PROs were to select samples of medical records from (1) all enrollees admitted to an inpatient hospital, (2) inpatient enrollees hospitalized for some of 13 specified medical conditions (such as a ruptured appendix), (3) non-trauma deaths in any setting, (4) patients transferred from a hospital with which the HMO does not have an agreement to one with which it does,² and (5) patients readmitted to an acute care hospital within 30 days of discharge from such a hospital.

The size of the sample for each review category depends on whether the HMO is on limited, basic, or intensified review.³ For example, PROs are required to review 5 percent of nontrauma death cases for an HMO on limited review, 10 percent for an HMO on basic review, and 100 percent for an HMO on intensified review.

After selecting the samples, the PRO requests the medical records from the HMO. The records are generally reviewed by nurses, who then refer potential quality problems for physician review. If the physician agrees that there is a quality problem, the case is to be discussed with the HMO, which is given the opportunity to provide additional medical information. At the end of this process, the PRO makes a final determination about whether a quality problem exists and, if so, the appropriate corrective action required. (See p. 22.)

PRO Review Hampered by Chronic Sampling Problems

The external review process can produce an unbiased, accurate assessment of the quality of care provided by risk HMOs only if the PRO review samples are drawn randomly from a data base of all medical services provided to Medicare enrollees. However, after more than 3 years of operation, the PROs still do not have access to the data necessary to effectively carry out their review responsibilities. This is due, in large part, to long-standing record-keeping inadequacies at most risk HMOs and HCFA's unsuccessful attempts to solve this problem.

¹As discussed on page 20, the PROs were also required to review quarterly subsamples of cases previously reviewed by the internal QAPs of HMOs on the limited review plan.

²Transfers were eliminated from PRO review requirements in August 1989.

³An HMO is put on limited review or basic review based on the PRO initial assessment of the HMO's internal QAP (see p. 19). An HMO is put on intensified review if the PRO's external review finds that at least 5 percent (with a minimum of six cases) of the HMO's cases reviewed for a 3-month period (or over the course of the contract) reveal inadequate treatment.

Incomplete Information on HMO Enrollees Receiving Inpatient Hospital Care— A Long-Standing Problem

The PRO contracts required them to use data from the fiscal intermediary (see p. 9) to select their review samples for Medicare HMO enrollees receiving inpatient hospital care. Intermediary data were an appropriate source for identifying Medicare beneficiaries receiving such care under the fee-for-service sector, but this was not the case for Medicare HMO enrollees.

Under the fee-for-service system, hospitals must submit all bills for inpatient services to the intermediary in order to be paid. Risk HMOs, however, pay the hospital bills for their enrollees, and neither the HMO nor the hospital has an incentive to submit copies of such bills to the intermediary because neither depends upon them for payment. Thus, intermediary data about HMO enrollees receiving inpatient hospital services are often incomplete. HCFA experienced problems in having HMOs submit “no-payment” bills long before the PRO review of risk HMOs began.

Starting in 1983, HCFA required HMOs to collect and submit various types of data needed to monitor their compliance with financial solvency requirements and calculate their reimbursement rates. In addition, under the PHS Act, all federally qualified HMOs were required to submit certain utilization data to HCFA, including information about Medicare enrollee use of inpatient hospital services. To collect the required statistical information about inpatient admissions, HCFA chose to have each HMO submit the no-payment bills to intermediaries, which in turn were to provide them to HCFA.

By early 1987, HCFA was aware that HMOs were not submitting all the no-payment bills to the intermediaries, and brought this problem to the HMOs' attention. HCFA reemphasized the importance of this reporting requirement—especially in light of the upcoming PRO review program. About that time, GHAA, an HMO trade association, reported to HCFA that most risk HMOs were incapable of submitting reliable no-payment bill data to intermediaries because of inadequate data collection and reporting systems.

HCFA apparently disregarded this report in implementing the PRO/HMO review, and continued to rely on risk HMOs to submit no-payment bills to the intermediaries. PROs would then use the intermediary data to draw their review samples. When the PROs expressed reservations about this decision in an April 1987 meeting, HCFA responded that HMOs were

required by statute and their contracts to comply with PRO review and that HCFA would try to ensure that they did so.⁴

The PROs experienced early problems in obtaining no-payment bills, and HCFA formed an internal study group to address the issue in the fall of 1987. The work group estimated in its January 1988 report that only 30 to 40 percent of all no-payment bills had been submitted to intermediaries between July and December 1987.

The work group proposed three alternatives to correct this problem. The first was to shift the reporting obligation from the HMOs to the hospitals. The second was to leave the reporting responsibility with the HMOs and request a legislative change to give HCFA intermediate sanction authority to penalize HMOs that did not submit the required data. The third was to leave the reporting responsibility with the HMOs, but also to permit HMO providers to submit no-payment bills to augment known shortfalls in the number of no-payment bills submitted by HMOs.

Effective August 1988, HCFA shifted the responsibility for reporting no-payment bills to the hospitals—even though the work group pointed out that hospitals had no contractual requirement and no incentive to submit these bills. As might be expected, this change did not correct the problem. In a February 1989 memo, HCFA concluded that, although there had been some improvement, the PROs were still unable to obtain “sufficient numbers of no-pay bills from which to draw samples to perform reviews.” HCFA estimated that only about half of the no-payment bills were being submitted.

We also reviewed hospital admission and discharge records at the 10 HMOs that we visited, and found that about 35,160 Medicare enrollees had received inpatient hospital care between August 1 and December 31, 1988. However, intermediary information provided to the PROs for this period included no-payment bills for about 21,600 admissions—about 61 percent of the number suggested by the HMO records.⁵

⁴If an HMO does not comply with the requirement to submit no-payment bills, the only punitive action available to HCFA is contract termination.

⁵While on average the PROs had access to about 61 percent of the no-payment bills, there was significant variation. For example, the California PRO received no-payment bills for about 85 percent of the admissions for two California HMOs, while the Minnesota PRO received no-payment bills for about 22 percent of the admissions for the two Minnesota HMOs.

HCFA's Current Sampling Plan for Inpatient Care Will Not Produce Reliable Results

In February 1989, HCFA introduced the "review augmentation" approach as a means of increasing the size of the PRO review samples related to inpatient hospital services.⁶ Under the plan, HCFA estimates the number of HMO enrollees that should be hospitalized during a given period and uses this estimate to project the size of the quarterly review sample for each HMO. Hospitals are still responsible for submitting no-payment bills to the intermediaries, and PROs are required to sample from the intermediary data. When the resulting sample for an HMO is smaller than HCFA's projection, the PRO is to make up the difference by selecting additional cases—first from the same intermediary data that produced the original sample and then, if necessary, by sampling from the HMO's list of Medicare enrollees.

This plan appears to increase the cost and complexity of the PRO review of risk HMOs without improving the reliability of the results. While this methodology should increase the number of PRO reviews, it requires additional effort on the part of HCFA, the HMOs, and the PROs to generate the review samples. More importantly, we question whether this cumbersome process will produce a reliable PRO assessment of quality of care at risk HMOs since the samples are still drawn from a universe that is incomplete and possibly subject to bias.

AMPRA, the professional organization representing PROs, has pointed out repeatedly to HCFA that mandating an "unproductive random sample" is not the solution to the long-standing data problems that have plagued the PRO external review of risk HMOs. AMPRA believes that the HMOs are the best source of no-payment bills. HMOs should have records of enrollees that are hospitalized in order to coordinate care, control utilization, and perform their internal quality assurance reviews. AMPRA feels that the requirement to collect and submit this information should be made part of the HMOs' Medicare contracts.

HMOs are required by statute and their contracts with HCFA to cooperate with PRO review. However, the only punitive action that can be taken against an HMO that does not submit the data needed for the PROs' review is contract termination. To rectify this situation, the HCFA component responsible for monitoring risk HMOs submitted a legislative proposal for fiscal year 1991 that would authorize HCFA to impose intermediate sanctions on HMOs that fail to comply with data requirements. Such sanctions would include suspension of enrollment, suspension of payments, and imposition of monetary penalties against noncomplying HMOs. In April

⁶This plan went into effect in April 1989 and covered inpatient admissions beginning in August 1988.

1990, HCFA officials told us that the legislative proposal had been withdrawn from consideration.

Ambulatory Reviews Also Limited, but Problems More Complex

The PROS' ability to review the quality of noninpatient hospital (ambulatory) care provided to Medicare enrollees has also been limited by sampling and records retrieval problems, but the data issues affecting ambulatory review are more complex than those affecting inpatient reviews.

First, the volume of ambulatory encounters—services that can range from routine office visits to outpatient surgery—makes sample design and selection a significant challenge. The situation is complicated further because there is no “uniform encounter” form (that could be used to identify all recipients of ambulatory treatment) similar to the no-payment bill used for inpatient hospital services (see p. 31). In addition, except for a few plans, HMOs do not have centralized data on ambulatory care, and obtaining and maintaining such information becomes especially problematic for HMOs that contract with physicians in the community (that is, IPA model HMOs) to provide health care services to enrollees. Finally, the quality of the medical records kept by HMOs and participating physicians vary widely.

In developing the scope of work for the PRO review of risk HMOs, HCFA recognized that, ideally, PROS should focus their ambulatory reviews on medical conditions and health care services for which quality problems are most likely to occur. HCFA also recognized, however, that the data needed were not available but hoped that the PROS, after gaining some experience with HMOs, might be able to suggest ways for carrying out the focused review of ambulatory care. When the PRO review of HMOs began in April 1987, HCFA asked the PROS to submit their plans for such focused review within 6 months of the beginning of their contracts.

In August 1987, HCFA also began meeting with a consortium consisting of representatives of the PRO industry (AMPRA) and the HMO industry (AMCRA and GHAA) to determine the most effective way of conducting ambulatory reviews. By November 1987, the consortium submitted a proposed ambulatory review plan that recommended random sampling from lists of active enrollees rather than focused review. Between December 1987 and March 1988, HCFA also received and reviewed 26 proposed plans for focused ambulatory review from the PROS.

After lengthy consideration of the consortium recommendation and the individual PRO proposals, in February 1989 HCFA began to revise the PRO contracts to add an approved plan for each for reviewing ambulatory care provided to Medicare HMO enrollees. Four PROs received approval to pursue focused review, while the rest implemented random sampling.⁷ HCFA has no effort underway or planned to promote the development of a centralized data base needed for focused review of ambulatory care at all HMOs.⁸

Because most PROs were just beginning ambulatory review at the time of our field work, we did not attempt to evaluate the effectiveness of random sampling from lists of enrollees. Early results, however, suggest that this approach, while expedient, may not be the most productive in terms of identifying quality problems. HCFA data for the first year of ambulatory review (through Aug. 31, 1990) show that the PROs using random sampling completed 13,962 reviews and found quality problems in only 56 (about 0.4 percent) of the cases. In comparison, PROs using the focused review methodology completed 933 reviews and found quality problems in 11 (about 1.2 percent) of the cases.

We believe that HCFA should continue to address the issue of PRO review of ambulatory care at risk HMOs, looking critically at the current review methodology and comparing it to the potential costs and benefits of focused ambulatory review. At the same time, HCFA should provide leadership in encouraging participating risk HMOs to begin collecting centralized data on ambulatory care. These data not only are necessary for PRO review but also would enhance HMO management and internal quality assurance activities.

Data Problems Limit the Effectiveness of the PRO External Review of Risk HMOs

The PRO external review of risk HMOs was intended to provide an independent, systematic evaluation of the care provided to HMO enrollees. Because of the problems in obtaining comprehensive data on the HMO services provided to Medicare enrollees, the PRO program has not met this objective. In a July 10, 1990, letter to HCFA, the president of AMPRA stated "PROs have yet to conduct enough review to make appropriate assessments about the quality of care in prepaid plans."

⁷The four PROs that received approval to pursue focused reviews did so because they assured HCFA that (1) the HMOs would provide needed ambulatory care data and (2) their proposed methodology focused on medical conditions and procedures that were susceptible to deficient care.

⁸In responding to a draft of this report, HHS said that HCFA had plans for—and has held meetings on—such a data base, but provided no further information about the plans.

Our work has shown specific instances in which the data problems limited the PROs' effectiveness in carrying out their contractual requirements. For example, the PRO contracts specify that they use the results of their reviews to develop profiles of aberrant HMOs or providers under contract with the HMOs. Profiling allows the PROs to focus on problem providers, thus bringing about more timely corrective action. At the time of our visit, four of the six PROs in our review had not begun the required profiling. Because of the sampling problems discussed earlier, one of the PROs had not reviewed any medical records, and two others had reviewed too few to make profiling meaningful.

Similarly, when the number of quality problems at a risk HMO reaches certain levels, the PROs are required to place the HMO under a corrective action plan and intensify the medical records review. Both of the HMOs that we visited in Florida had exceeded the specified thresholds for quality problems, but only one had been placed on intensified review. PRO officials told us that they lacked confidence in the validity of the review results because the universe of inpatient hospital admissions was understated; thus, they were reluctant to place the second HMO on intensified review.

We reviewed HCFA's March 1989 HMO Data Summary Report and identified several other instances in which HMOs appeared to have exceeded the established thresholds but were not placed on intensified review. Because this report lists quality problems by state rather than by HMO (see below), we contacted the responsible PROs and confirmed that at least four other risk HMOs were not placed on intensified review when they should have been. Again, this was due in part to the PROs' lack of confidence in the validity of their review results stemming from the sampling problems.

HCFA Not Using Results of PRO Review in Its HMO Oversight Activities

The PRO review program for risk HMOs, while behind schedule in terms of medical reviews completed, has nevertheless identified quality-of-care problems at risk HMOs (see p. 22). HCFA, however, has not incorporated this information into its HMO compliance monitoring process.

PRO contracts require that they report monthly to HCFA the data from their quality reviews of risk HMOs. The usefulness of this information in HCFA's oversight of risk HMOs is diminished because HCFA requires that the data be aggregated by state rather than by HMO. The PRO reports include the total number of confirmed quality problems for all HMOs in each state by severity level and category of review.

The HMO quality data are reported to HSQB, the HCFA component responsible for overseeing the PRO contracts. Because the data are not HMO-specific, the reports are not routinely requested by or made available to OPHC, the HCFA component responsible for monitoring the HMOs. We were told that the aggregated reporting format was used because of concern about the (1) validity of data from a new untested review process, (2) potential for misinterpretation of data if released prematurely to the public, and (3) lack of a comparable data reporting process for the fee-for-service sector.

In January 1989, HCFA began requiring PROs to report data on the results of their reviews by HMO. It was planned, however, that the information would be encrypted by the PRO before the report was sent to HCFA. No HMO-specific data summary reports were available as of September 1990.

To provide a comprehensive view of the performance of individual risk HMOs, we believe that information from the PRO reviews—if HMO-specific—should be linked with other data on HMOs developed by HCFA. These other data include data from (1) HCFA's compliance monitoring process and (2) the Beneficiary Inquiry Tracking System—a computerized system that tracks beneficiary complaints, and inquiries about HMO services. Part of the system involves categorizing the complaints, which allows HCFA to determine how many relate to quality of care and to which HMOs they pertain.

Conclusions

The PROs' ability to assess the quality of care provided by risk HMOs has been impeded by data problems since this external review program began in 1987. These problems persist in part because HCFA has not provided the strong central leadership needed to correct them.

PROs have been unable to obtain comprehensive information about Medicare HMO enrollees receiving inpatient hospital care—the starting point for most of their required reviews. While HMOs should be expected to have this information, HCFA has not sought the legislative authority needed to ensure that they provide it to the PROs. Instead, HCFA has undertaken a series of unproductive alternatives, including the “augmentation” sampling plan being used currently by the PROs. In addition, there is no centralized data base that the PROs can use to review ambulatory care. HCFA has no effort underway to promote the development of such a data base.

HCFA has lost the marginal benefit that could otherwise have been derived from the PRO review because it has not incorporated the results of these efforts into its own HMO oversight process. Data on PRO-identified problems are not reported to HCFA on an HMO- or provider-specific basis and are not routinely provided to the HCFA component responsible for monitoring risk HMOs.

In summary, after more than 3 years of operation, the PRO external review program has done little to enhance HCFA's oversight of risk HMOs and has not provided the intended assurance that Medicare HMO enrollees are receiving quality health care.

Recommendation to the Congress

Although risk HMOs are required to cooperate with PROs, we recommend that the Congress amend the Social Security Act to give HCFA explicit authority to impose remedies—such as suspending enrollment or payments or imposing civil monetary penalties—to help assure that risk HMOs comply in collecting and submitting the inpatient hospital information needed by the PROs to carry out their review responsibilities.

Recommendations to the Secretary of HHS

We recommend that the Secretary direct the Administrator of HCFA to (1) critically monitor the results of the PRO review of ambulatory care at risk HMOs as part of an ongoing effort to identify the most effective way of doing such reviews, (2) provide leadership in encouraging participating risk HMOs to begin collecting centralized data on ambulatory care provided to Medicare enrollees, (3) require PROs to report the results of their quality reviews by specific HMOs, and (4) link this information with that available from HCFA's compliance monitoring process and the Beneficiary Inquiry Tracking system to provide a more complete profile of HMOs with risk contracts.

Agency and Association Comments and Our Evaluation

HHS

HHS did not respond directly to our recommendation that HCFA monitor the results of PRO review of ambulatory care in order to identify the most effective way of doing such reviews. However, HHS disagreed with

our second recommendation—that HCFA provide leadership in encouraging participating risk HMOs to begin collecting centralized data on ambulatory care provided to Medicare enrollees. HHS stated that a requirement to maintain centralized ambulatory records would be especially problematic for group and IPA model HMOs. (See app. II.)

Contrary to HHS's interpretation, we are not recommending that centralized medical records be maintained. Rather, we are recommending that HCFA work with HMOs to develop the minimum centralized data needed by the PROs to identify (1) Medicare enrollees who receive ambulatory care and (2) the type of ambulatory care provided.

However, HHS apparently agrees with the need to develop centralized data on ambulatory care, commenting that HCFA plans for—and has held meetings about—such a data base. HHS provided no further information on the plans, and we note that, as of November 1990, HCFA officials told us there were no plans for such a data base.

HHS did not respond directly to our third recommendation that PROs should be required to report the results of their quality reviews by specific HMO. It agreed with our recommendation that such information should be linked with that from HCFA's compliance monitoring process and the Beneficiary Inquiry Tracking System. However, HHS did not comment on whether it intended to work toward this goal.

GHAA

GHAA generally agreed with our conclusion that PROs must be able to identify which Medicare enrollees receive services—and the type of services provided—if they are to effectively monitor quality of care at risk HMOs. However, GHAA did not agree that HMOs should be responsible for providing the needed information.

GHAA also identified several policy options for conducting external review that are discussed in appendix III.

AMCRA

AMCRA did not specifically address the recommendations discussed in this chapter. However, AMCRA believes that the PROs' overall assessment of quality of care at risk HMOs has failed because of their "lack of methodological expertise and competence." (See app. IV.)

We did not have to evaluate the capability of the PROs or the adequacy of their review methodology to conclude that the results of their reviews

were invalid. Data and sampling problems, as discussed in this chapter, jeopardized the success of this program from the outset. Moreover, AMCRA provides no evidence to support its assertion that PROs lack the competence to assess the quality of care at risk HMOs. AMCRA is apparently willing to accept the competency of the PROs and the results of their reviews in certain instances, citing the results of the PRO review of ambulatory care as an indication of the lack of quality problems at risk HMOs (see p. 63).

AMPRA

AMPRA stated that we have accurately and thoroughly documented the present deficiencies in the external review program of risk HMOs. It concurred with our recommendation that the Congress provide HCEFA with explicit authority to sanction HMOs that do not comply with requirements to collect and provide information needed to carry out the review program. (See app. V.)

PROs and HMOs Included in Review

State	PRO	HMO
California	California Medical Review, Inc.	FHP Pacificare
Florida	Professional Foundation for Health Care, Inc.	Health Options of South Florida Humana Medical Plan
Georgia	Georgia Medical Care Foundation	Kaiser Permanente of Georgia
Illinois	Quality Quest, Inc.	Health Chicago Share Illinois
Minnesota	Foundation for Health Care Evaluation	Med Centers Physicians Health Plan
North Carolina	Medical Review of North Carolina	Kaiser Plan for North Carolina

Comments From the Department of Health and Human Services

Note: GAO comments supplementing those in the report text appear at the end of this appendix.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

JAN 29 1991

Ms. Janet L. Shikles
Director for Health Financing
and Policy Issues
United States General
Accounting Office
Washington, D.C. 20548

Dear Ms. Shikles:

Enclosed are the Department's comments on your draft report, "Medicare: PRO Review Does Not Assure Quality of Care Provided by Risk HMOs." The comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "R. Kusserow".

Richard P. Kusserow
Inspector General

Enclosure

Comments of the Department of Health and Human Services
on the General Accounting Office Draft Report
"Medicare: PRO Review Does Not Assure
Quality of Care Provided by Risk HMOs"

Overview

GAO states that, after more than 3 years of operation, the peer review organization (PRO) review program has not provided the intended assurance that Medicare beneficiaries enrolled in risk-based health maintenance organizations (HMOs) are receiving quality health care. In general, GAO points out some of the problems we have identified through our own internal analysis. However, GAO fails to recognize the safeguards the Health Care Financing Administration (HCFA) has set up within the HMO program to address these problems. These activities ensure that systems are in place to monitor the quality of care to Medicare beneficiaries, as well as commercial enrollees. Central to these is the routine monitoring strategy.

Initiated 1987, the routine monitoring strategy included development and evaluation of a broad range of the following monitoring activities.

- o Comprehensive site visits were conducted biennially to check the HMOs compliance with all the Medicare requirements. Included is an evaluation of the HMO's Quality Assurance Program (QAP).
- o A national automated beneficiary inquiry tracking system allows HCFA to collect and track information on beneficiary questions and complaints.
- o A survey of a sample of disenrollees was conducted to determine the reasons these Medicare members left the HMOs. HCFA will use the results to determine the need for routinely conducting similar surveys.
- o A management information system was initiated which links financial, enrollment and other HMO data. With full implementation of the last phase of this project, HCFA also will be able to track all the activities related to HMO corrective actions.

See comment 1.

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Comments From the Department of Health
and Human Services

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Simultaneous with the development of these activities, HCFA was working with PROs and HMOs to carry out review of risk-based HMOs. Over the last year, HCFA has evaluated the PRO review process to determine where changes are necessary. This effort is consistent with HCFA's pledge to evaluate the program based on operating experience. That evaluation led HCFA to explore reform of the program. HCFA recently distributed a reform proposal which addresses not only GAO's concerns but those of beneficiary advocacy groups, and the HMO industry.

GAO believes the lack of assurance in the review program can be attributed to a lack of strong central management. GAO bases its belief, in part, on HCFA not requiring PRO review of all HMOs' Quality Assurance Plans (QAPs). HCFA designed the PRO review program according to the legislative intent that the basis of the program should be individual case review. The PRO's purpose in reviewing cases was to discern whether HMOs were delivering services that met recognized standards. HCFA's role was to assess the QAP as a required part of the qualifications and monitoring processes.

Three years ago, when GAO began its study, HCFA had just begun the routine monitoring strategy. Since then, HCFA has conducted a comprehensive on-site evaluation of every HMO contracting to provide Medicare services. Each biennial site visit included an analysis of the internal QAP against regulatory requirements. In every case, HCFA assessed the QAP to ensure the HMO reviewed and corrected problems it identified. The HMO is required to develop a corrective action plan for any deficiencies identified during this analysis. HCFA first determines the acceptability of the plan and then oversees the HMO's progress in correcting any deficiencies.

At the beginning of PRO review, HCFA provided the HMO the option of having the PRO also review the QAP. HCFA set up this option to focus and lessen review only for HMOs with strong QA systems. Upon an HMO's request, the PRO determined the review level based on an "initial analysis" of the QAP. HCFA allowed the PRO to develop, with the aid of community practitioners, its own criteria for initial analysis. When the PRO provided results, HCFA did review them to determine whether the shortcomings involved any regulatory requirements. HCFA conducted follow-up of

See comment 2.

See comment 3.

Page 3

those cases where there were potential violations of regulations. However, because the PRO requirements were not consistent with regulatory requirements, HCFA determined that its internal site visit analysis of QAPs was a more productive use of both HCFA's and the PRO's resources.

GAO goes on to state that the record-keeping inadequacies at most risk-based HMOs have jeopardized the PRO review process. GAO is referring to difficulties in getting accurately completed inpatient bills. HCFA's evaluation found that all parties involved (hospital, fiscal intermediaries and HMOs) had processing difficulties. The impact of these difficulties was an inadequate database of inpatient bills. HCFA's analysis showed that, due to the multiple potential problem areas, achieving the processing rate necessary to have a statistically valid review process would require significant resources. Therefore, in the interim, HCFA will work toward a long term goal of outcomes analysis using a standard data set. Thus, HCFA developed the reform proposal which will make the PRO review process complementary to our current QA statutory authority.

See comment 2.

In addition, it should be noted that the inpatient bill is not the only source of data about HMO care. The PROs use other data sources to review ambulatory care, care before death for deceased beneficiaries, and complaints.

Finally, GAO states that HCFA has lost the marginal benefit that could otherwise have been derived from PRO reviews that have been done because it has not incorporated the results of these efforts into its own HMO oversight process. Although GAO criticizes HCFA for not linking PRO data to routine monitoring, HCFA in fact has been carefully developing a process to do just that. HCFA has moved slowly to ensure the privacy of the data and their accurate and fair presentation.

See comment 4.

GAO Recommendation

We recommend that the Secretary of HHS direct the HCFA Administrator to:

- amend the HMO and PRO contracts to make mandatory the PRO review of QAPs of all risk HMOs participating in the Medicare program. This requirement should include provisions for (1) HMO corrective action and PRO follow-up where the HMO QAP cannot demonstrate the capacity to identify and correct quality of care problems, and (2) periodic PRO monitoring of those QAPs found to be effective;

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Department Comment

The legislation requiring PRO review of services provided to Medicare beneficiaries enrolled in risk HMOs does not require a review of the QAP; rather, the emphasis was placed on review of actual services provided to patients. Although the initial scope of work detailing the requirements for PRO review of HMOs included a provision which allowed HMOs to request that the PRO review the HMO's QAP, this was not the central component of the scope of work. Nowhere in the enabling legislation or accompanying report language is mention made that Congress intended that there be a comprehensive mandatory rereview of previously reviewed and approved internal QAPs. Furthermore, GAO has ignored the fact that QAPs are reviewed as part of the Medicare HMO qualifications and routine monitoring processes; consequently, further PRO review would be redundant. Given this, the intent of the authorizing legislation was clearly to set up a system whereby PROs would review the quality of services provided to Medicare risk HMO enrollees. The legislation specified the use of PROs in the review activity and the expertise and experience of the PROs was recognized by all parties as lying in the area of individual case review, not in the determination that HMO internal quality assurance programs were effective. Approval of internal QAPs by PROs was limited to those situations where an HMO could demonstrate that its internal program was equal (or superior) to the PRO's review plan.

GAO Recommendation

- develop, in cooperation with the PRO and HMOs, uniform review guidelines to be used by the PROs in assessing the effectiveness of HMO QAPs; and

Department Comment

At the present time, HCFA has guidelines used to perform exactly this function. We are working with HMOs to create a minimum data set and a revised QAP system that would be data driven and outcomes-oriented.

GAO Recommendation

- review the requirements for the PRO external quality review of HMO medical records and make necessary adjustments to ensure that review levels are commensurate with the effectiveness of the QAPs. That

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is. those HMOs with QAPs that can demonstrate the capacity to identify and correct quality problems should be subject to lower levels of external PRO review.

Department Comment

We believe that in the long term we could do this. Since we are hampered by a lack of uniform outcome data to assist in the assessment of the QAPs, we believe that this could not be done at the present time, but as noted above, we are working to develop such a capability.

GAO Recommendation

We recommend that the Secretary direct the Administrator of HCFA to (1) critically monitor the results of the PRO review of ambulatory care at risk HMOs as part of an ongoing effort to identify the most effective way of doing such reviews. (2) provide leadership in encouraging participating risk HMOs to begin collecting centralized data on ambulatory care provided to Medicare enrollees. (3) require PROs to report the results of their quality reviews by specific HMOs, and (4) link this information with that available from HCFA's compliance monitoring process and the Beneficiary Inquiry Tracking system to provide a more complete profile of HMOs with risk contracts.

Department Comment

HCFA's evaluation of HMO quality of routine ambulatory care suggests that quality of care is superior in HMOs compared to the fee-for-service setting. Requirements for centralized ambulatory records is especially problematic for group and IPA model HMOs. To pursue centralized ambulatory records can distract from the primary objective of outcomes oriented review. We strongly disagree with GAO and believe HMO ambulatory review should be commensurate with ambulatory review in the fee-for-service setting. We agree, however, that all data should be linked to other available data on HMO performance.

Other Matters

- o GAO states that the PRO external review process can produce an unbiased, accurate assessment of the quality of care only if the PRO review samples are drawn randomly from a data base of all health care services

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provided to Medicare enrollees. This is what we are proposing in our new HMO scope of work because we too believe that a random sample of users of services will yield the most meaningful review results.

- o GAO states that HCFA has no effort underway or planned to promote the development of a centralized data base needed for focused review. This is not true. HCFA not only has plans for such a data base but has had preliminary meetings with representatives of the HMO industry about its plans.

See comment 2.

The following are GAO's comments on HHS's letter dated January 29, 1991.

GAO Comments

1. HHS stated that the report did not recognize HCFA's HMO oversight activities that serve to assure the quality of care provided to Medicare HMO enrollees.

While HCFA's HMO oversight activities were not the subject of this report, we discuss them on pages 12 and 18. The Congress believed that, in addition to HCFA's monitoring activities, an external peer review program was needed to provide an independent medical assessment of the quality of health care provided to Medicare beneficiaries in risk HMOs. The focus of this report is the extent to which PRO review has met its intended objectives.

We have reviewed HCFA's HMO oversight activities in the past and, in an August 1988 report, identified several weaknesses in HCFA's monitoring program. We are again evaluating these activities as part of another study, and preliminary results suggest that not all problems have been corrected. For example, HCFA notified officials at one risk HMO of significant deficiencies in several key areas of their operation—such as quality assurance and marketing—in April 1989. However, it took HCFA almost 2 years (until Jan. 1991) to approve a corrective action plan to address the marketing deficiency. As of February 1991, HCFA had not approved a plan to correct the remaining deficiencies.

2. HHS stated that HCFA is reforming the PRO/HMO external review process and believes that the proposed changes will address many of our concerns. We recently reviewed the HCFA proposal that would change the process used by the PROs to select cases for review. Rather than relying on no-payment bills as the data source, the PROs will select their samples from lists of HMO enrollees.

HCFA will provide each PRO with the names of all Medicare enrollees to be evaluated. The PRO will first select a sample from the list and then ask each HMO to determine if the selected enrollees received treatment during the previous 6 months. For enrollees who have, the HMO will be expected to obtain the medical records (from the hospitals or the physicians) and provide them to the PRO. If necessary, the PRO will return to the original list and select additional enrollees to replace those not receiving health care services.

We have a number of concerns about the proposal. Most importantly, the proposed methodology will be affected by the same basic problem that has hampered the current PRO/HMO review process—the lack of centralized HMO information on enrollees receiving either inpatient or ambulatory care. As discussed in chapter 3, many HMOs do not have information systems to provide such basic data as the names of enrollees who have been hospitalized, the dates of their hospitalization, or the medical conditions for which they were hospitalized. If HMOs maintained such information currently, there would be no need to change the PRO sampling and review methodology.

Thus, under the HCFA proposal, many HMOs will be required to contact participating providers to determine which of the enrollees selected for review have received services and the type of services provided. This could be especially problematic in IPA model HMOs because of the number and dispersion of the physicians involved. Further, this process relies on the accuracy and completeness of the records of the individual physicians that treat Medicare enrollees. In addition to burdening the HMOs and subproviders, such a system introduces a potential for bias in the selection of review cases. Neither HCFA nor the PROs appear to have a mechanism to verify the enrollee information provided.

We are also concerned that the proposed methodology would not allow PROs to focus on specific high-risk medical conditions or procedures. In describing the proposed changes, HCFA acknowledges that the current PRO/HMO review methodology, using specific review categories (see p. 30), appears to be “more effective in identifying specific problems” than a process that uses randomly selected enrollees. The proposal also seems inconsistent with impending changes to the PRO review of fee-for-service health care that are designed to focus on problem areas identified through objective criteria.

In summary, we believe that the proposed change to the PRO/HMO review methodology—like the numerous changes that have preceded it—reflects HCFA’s inability to address the underlying data problems that have hampered this review program from the outset. As a condition for participating in Medicare, federal regulations require risk HMOs to have a quality assurance plan that uses “systematic data collection” to identify patterns of suspected aberrant care, such as underutilization. Thus, we do not understand how HMOs can meet this and other regulatory data requirements and yet be unable to provide PROs with the basic information required to select their review samples.

3. HHS contends that PRO reviews of QAPs duplicate reviews performed by HCFA staff.

We do not agree. As discussed on page 18, HCFA's reviews focus on QAP structure, not on effectiveness. PRO review includes a reevaluation of patient medical records that were previously reviewed under the QAP. By reviewing medical records, the PRO is better able to determine if the QAP is performing effectively.

HHS also indicated that HCFA reviewed the results of the PRO assessments of QAPs and conducted follow-up where the PRO identified potential violations of regulations.

This contradicts information that we received during our review. On two separate occasions—including our exit conference—HCFA officials told us that they had followed up on only 1 of 36 QAPs.

4. HHS stated that HCFA has been slowly developing a process to incorporate data from the PRO reviews with those available from its own oversight process.

We agree with HHS that this effort has proceeded slowly. It has been almost 4 years since the PRO review of HMOs began, and HCFA is still unable to link information provided by the PROs with information from its compliance monitoring process and its beneficiary complaints system.

Comments From the Group Health Association of America, Inc.

Note: GAO comments supplementing those in the report text appear at the end of this appendix.



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President and Chief Executive Officer
James F. Doherty

January 18, 1991

Janet L. Shikles
Director for Health Financing
and Policy Issues
United States
General Accounting Office
Washington, D.C. 20548

Dear Janet:

Thank you for providing GHAA with the opportunity to review GAO's draft report entitled "Medicare: PRO Review Does Not Assure Quality of Care Provided by Risk HMOs." We have comments regarding the draft report's overall conclusions and recommendations, as well as some suggestions for making the background material presented in Chapters 2 and 3 more complete.

GAO CONCLUSIONS AND RECOMMENDATIONS

We would like to offer some suggestions pertaining to the external review of HMO internal QA programs and to the submission of inpatient and ambulatory data for HMO enrollees.

External Review of QA Programs

GHAA agrees with GAO's conclusion that all Medicare risk HMOs should be subject to an external review process that assesses the adequacy of their internal quality assurance program. The HMO industry has long recognized that a strong internal quality review system is essential to insure and improve the accessibility and appropriateness of patient care to all enrollees. Through the external review process, HCFA and other payers/regulators can provide incentives and constructive feedback to HMOs that will promote the further development of HMO internal QA systems.

We do, however, feel it is imperative that GAO identify and analyze the various policy options for conducting external reviews of HMO internal QA programs before recommending that such review programs be established in all PROs nationwide. We seriously question whether PROs

See comment 1.

Appendix III
Comments From the Group Health
Association of America, Inc.

Needless to say, there are limits on the extent to which HMOs are able to require hospitals and physicians/medical groups to maintain medical records in a certain fashion; to abstract, code and automate certain data; and to make such data available in a timely fashion. In almost all communities, HMOs are not the dominant mode of delivery. Although we expect this to change over time as HMOs acquire greater market share, for the foreseeable future, many individual HMOs will constitute only a fraction of a given hospital's or physician's patient load.

At present, hospitals, not HMOs, are required to submit no-pay bills for HMO Medicare admissions. No-pay bills available to PROs fall short of the total universe of HMO inpatient episodes for at least two reasons: fiscal intermediaries do not always process the no-pay bills they receive, and hospitals do not always comply with the requirement.

We do not know the extent to which fiscal intermediaries fail to process no-pay bills in a timely fashion. It is our understanding that HCFA's Office of Prepaid Health Care and Health Standards and Quality Bureau attempted to estimate and take actions to resolve this problem about two years ago. We are not aware of the current status, but as long as intermediaries are under pressure to make payments on fee-for-service UB82s within a limited number of days, it seems reasonable to assume that these claim forms will receive the highest priority and no-pay bills a secondary priority. Moreover, if the Office of Management and Budget fails to release contingency funds for Medicare contractors, it is likely that there will be even greater problems in processing no-pay bills as fiscal intermediaries struggle to process fee-for-service claims (see Medicine and Health, January 14, 1991).

It is correct that hospitals have little incentive to submit no-pay bills. One way to resolve this problem is to levy sanctions on those hospitals that fail to submit the no-pay bills and/or to temporarily suspend Medicare payments for fee-for-service inpatients. It is worth noting that the submission of no-pay bills does not impose additional burden on hospitals that they do not currently have for fee-for-service Medicare beneficiaries. If HMO Medicare beneficiaries had not selected an HMO, they would be receiving services through the fee-for-service sector and hospitals would be submitting UB-82 claims for services rendered.

The second option, which the draft report advocates, is to transfer the responsibility to HMOs and give HCFA the authority to levy sanctions on those HMOs that fail to comply. We believe this option is neither desirable for HMOs nor Medicare beneficiaries. The federal government is in a stronger position to elicit no-pay bills from hospitals, possibly through the use of sanctions, than are individual HMOs that generally have far less influence and leverage. Hospitals will undoubtedly charge HMOs to submit the

See comment 6.

Appendix III
Comments From the Group Health
Association of America, Inc.

UB82 data and in most communities where HMOs are not a dominant provider, hospitals may charge excessive amounts for these services. Fees paid by HMOs to hospitals increase administrative costs and reduce the monies available for beneficiary care.

Yet another policy option that would resolve both the problems associated with the submission of no-pay bills and the processing of the no-pay bills by intermediaries would be to adopt a new sampling strategy for PRO review that is not dependent on UB82 data. This option is currently being considered by HCFA. In June 1990, HCFA released two proposals for modifying PRO review and requested comments from interested parties. One of these proposals (proposal I) recommended that PROs review the care provided to a random sample of enrollees. A related component of this same proposal is to develop an alternative qualification process for HMOs that would mandate the collection of a minimum clinical dataset. GHAA supports this proposal in part because it introduces some short-term refinements to the PRO program, but more importantly because it would put in place a process to identify the inpatient and ambulatory data needed to facilitate external and internal HMO quality review. If the Medicare program intends to make these refinements in its oversight processes during the next one to two years, it would probably not be wise to introduce changes in the responsibility for the submission of no-pay bills at this time.

Because there are several policy options that have not been thoroughly analyzed, we feel it is premature for GAO to recommend that responsibility for UB82s be shifted to HMOs and that sanctions be levied on those HMOs that fail to comply with this requirement. Not only are there alternative policy options that should be considered, there are also many unanswered questions regarding the no-pay bill issue, including:

- o Does the no-pay bill problem stem from a minority of hospitals or does it involve most of the hospital industry?
- o Why is it so difficult for hospitals to submit no-pay bills? If HMO Medicare beneficiaries had not enrolled in an HMO they would be receiving services through the fee-for-service system and hospitals would be completing and submitting UB82s. The little anecdotal information we have regarding this problem is that it apparently involves the addition of a new data field to hospital billing systems so that no-pay bills can be "tagged" and diverted from entering the hospital's accounts receivable systems. We have no information on the costs associated with making the necessary modifications to the hospitals' information systems.

See comment 6.

See comment 2.

have the clinical or administrative expertise and experience required to conduct an external review of an HMO's quality assurance program. The draft report does not include any factual information to substantiate its assertion that PROs have the "medical capability to evaluate the effectiveness of HMO QAPs" (pg. 3).

GHAA believes that such an external review program should:

- o be conducted by a team of HMO experts including at least one physician in an HMO senior medical management position experienced in establishing and managing a quality assurance and improvement system in an HMO; and
- o assess compliance with a well-defined set of standards that focus on the essential characteristics of a quality assurance and improvement system.

See comment 3.

There are compelling reasons to centralize this responsibility in one or a limited number of national organizations. First, an external review process cannot be credible if it rests on the judgements of physicians who have little knowledge of HMO internal systems and/or who have conflicts of interests (e.g., employed by or under contract with an HMO that competes with the HMO undergoing review) in conducting such reviews. Physicians possessing the requisite credentials are limited in number, and generally must be drawn from geographic areas other than the state in which the HMO resides. Consequently, the review organization must have access to a national pool of physician experts.

Second, limiting the number of organizations engaged in external quality review would result in greater consistency in applying review standards. As you are aware, there is currently much variability across PROs in the conduct of QA program reviews and of case reviews, thus creating an inequitable situation across HMOs. In addition, many HMOs are a part of national or regional chains that strive to establish a degree of consistency in their QA programs and health care delivery systems in general. It is difficult for these national chains to respond to different external review programs sponsored by the various PROs. It should also be noted that the conduct of a thorough QA program review requires that the review team have some knowledge of the central HMO governance and management structure as well as the plan level QA program.

Third, it would be inefficient use of scarce health care resources to attempt to establish review programs in the thirty PROs involved in HMO review. A national organization would benefit from being able to recruit more highly trained senior management staff and from economies of scale associated with designing and implementing

The following are GAO's comments on GHAA's letter dated January 18, 1991.

GAO Comments

1. GHAA stated that we should have identified and analyzed the various policy options for conducting external reviews of QAPS.

Our objective was not to analyze policy options for conducting external reviews of HMOs' QAPS, but rather to determine the extent to which the PRO program has provided HCFA with assurance that Medicare beneficiaries in risk HMOs are receiving quality treatment. It was in this broader context that we considered how the PROs could have been used to evaluate HMO QAPS. We evaluated the PRO option because

- it was reasonable that the PROs perform this function as a starting point for establishing the subsequent level of medical case review,
- OMB proposed using the PROs in this capacity and HCFA included mandatory QAP review as part of its request for proposal to prospective PROs (see p. 19), and
- HCFA set congressional expectations concerning the PRO review of QAPS (see p. 19). In our opinion, the HCFA Administrator's June 1987 letter to Senator John Heinz established the presumption that HCFA would require the PROs to review each QAP as a basis for determining which plans qualified for limited review.

We believe—and GHAA agreed—that all Medicare risk HMOs that have not done so should subject their QAP to an external review. We recommended that this review be done by the existing PROs because the structure is in place to accomplish this function. However, other review entities could perform such reviews as long as the integrity and fairness of the review process, and the validity of the review results, are ensured. As a minimum, this would require independent and qualified reviewers and a uniform methodology based on explicit standards.

2. GHAA stated that it questions whether the PROs have the clinical and administrative expertise and experience to conduct reviews of QAPS, and that our report does not include factual information to substantiate its assertion that PROs have the medical capability to evaluate the effectiveness of QAPS.

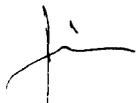
As we stated in our report, PROs are staffed with nurses and physician reviewers (see p. 30), and the evaluation of QAPS included a review of medical records previously reviewed by the HMO's QAP. We fail to see

**Appendix III
Comments From the Group Health
Association of America, Inc.**

In summary, we too share the concern that some of the necessary clinical data may not yet readily be available in a timely fashion to support quality review (both external and internal to the HMO). But we think the problem is a complicated one and we are not confident that shifting the responsibility for UB82 submission will achieve the desired outcomes. We encourage GAO to look more closely at this problem before recommending this course of action.

We hope these comments are helpful, and appreciate this opportunity to provide input. Please do not hesitate to call us if you have questions regarding our comments.

Sincerely,



James F. Doherty
President and Chief Executive Officer

We are uncertain if GHAA is suggesting that the NCQA accreditation process could satisfy the objective of QAP review. If so, we question whether NCQA, an organization affiliated with the HMO industry, would meet the requirements for independence that we believe must characterize QAP reviews.

5. GHAA stated that our report is inadvertently misleading in its reference to “record-keeping inadequacies” on the part of HMOs, pointing out that most HMOs do not possess or control enrollees’ medical records. To the contrary, GHAA indicates that inpatient records are kept at the hospital, while ambulatory records are kept at the office of treating physicians. As a result, GHAA points out that most HMOs are not in a position to (1) require hospitals and physicians to maintain records in a certain fashion, (2) abstract, code, or automate the data, or (3) make the medical data available (to the PRO) in a timely manner.

Our use of the term “record-keeping inadequacies” (see p. 30) does not refer to medical records. We recognize that the medical records are often widely dispersed, particularly in the case of IPA model HMOs, which have constituted the majority of risk HMOs (see p. 10). Because an enrollee’s medical records may be scattered among several providers, the PROs (and the HMOs) may have a difficult time tracking down and reviewing them. Although an impediment to performing reviews, however, obtaining access to these medical records is a secondary problem.

Our use of the term “record-keeping inadequacies” refers to a more basic problem. We believe many HMOs—particularly IPA models—do not have management information systems capable of capturing and providing information identifying which of their Medicare enrollees have been hospitalized, the dates of hospitalization, and the medical condition treated.

Federal regulations require each participating HMO to develop a “health (including medical) recordkeeping system through which pertinent information relating to the health care of the patient is accumulated and is readily available to appropriate professionals.” Regulations also require risk HMOs to have a quality assurance plan that uses “systematic data collection” to identify patterns of suspected aberrant care, such as underutilization. Thus, we do not understand how HMOs can meet these regulatory requirements and yet be unable to provide PROs with the basic information required to select their review samples.

what further information is needed to substantiate that doctors and nurses are capable of reviewing medical records and other data to make judgments about whether a QAP is able to identify and correct quality problems.

GHAA also stated that reviews of QAPs should be conducted by a team of HMO experts, including at least one physician in an HMO senior medical management position with experience in managing a QAP.

In our opinion, the essence of an evaluation of a QAP ultimately comes down to an assessment of health care and a determination of how quality-of-care problems are identified and corrected. We fail to see why HMO affiliation or HMO experience is a prerequisite to evaluating a QAP's effectiveness.

3. GHAA cites a number of reasons for centralizing the responsibility for QAP reviews into one or a limited number of national organizations. Its reasons include: improved access to a national pool of physicians with knowledge of HMOs, greater consistency in applying review standards, and improved efficiency in the use of scarce health care resources.

We would not disagree with GHAA's point that the idea of centralizing the responsibility for QAP reviews could have merit. We believe that the important point is not so much who reviews the QAPs or how many entities exist to do the reviews. Our concern is that each QAP should be independently reviewed, that the review process should yield valid results, and that QAPs with recognized inadequacies should be corrected.

4. GHAA stated that it believes that any mandatory QAP review program should be acceptable to both HCFA and other concerned parties. It noted that the National Committee for Quality Assurance (NCQA) has made progress in developing an HMO accreditation process and that the National Association of Health Maintenance Organizations Regulators has recently completed work on a set of standard guidelines for reviewing QAPs.

We agree with GHAA that the methodology used to review QAPs should be developed with input from all affected parties and should minimize duplication. As we indicated in our previous response, however, our primary concern is that each QAP be subjected to a valid independent assessment.

Comments From the American Managed Care and Review Association

Note: GAO comments supplementing those in the report text appear at the end of this appendix.



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January 22, 1991

Janet Shikles
Director of Health Financing and Policy Issues
General Accounting Office
441 G Street, N.W. Room 6858
Washington, D.C. 20548

Dear Ms. Shikles:

Thank you for the opportunity to comment on the GAO draft report on Peer Review Organization (PRO) review of managed care entities with Medicare risk contracts. The American Managed Care and Review Association (AMCRA) appreciates the opportunity to work with the federal government on this important issue.

By way of background, AMCRA is the national trade association for the managed health care industry. Its membership includes health maintenance organizations (HMOs), competitive medical plans (CMPs), independent practice associations (IPAs), preferred provider organizations (PPOs), utilization review organizations (UROs) and other entities which provide or arrange for health care services in a managed care setting as opposed to the traditional fee-for-service system. We represent over 400 members who serve over 25 million enrollees in every state and each of the United States territories. AMCRA member companies offer Medicare services to over 470,000 beneficiaries; 41 percent of the total Medicare managed care enrollment. One of AMCRA's priority issues in the Medicare managed care program has been reform of the PRO system.

We are distressed that the GAO report does not address the baseline issue of whether the established complaints and quality problems of managed care risk contractors justifies the resources expended in the PRO review program over the last three years. With the increasing stress on the federal budget and the mandate for government to assure cost-effectiveness and value in all of its expenditures, AMCRA feels GAO has a responsibility to assess whether the PROs' approach to review of managed care entities is appropriate in relation to the complaints expressed about the care provided by those contractors. This report notes that HCFA data identified quality problems in only .4 to 1.2 percent of the cases reviewed within managed care contractors. Yet, GAO proceeded on the assumption that this reflected a flaw in the evaluative procedure, not that it could in fact reflect a lack of quality problems. It is

See comment 1.

6. GHAA stated that because there are numerous policy options available for HCFA to resolve the no-payment bill problem, it was premature for us to recommend that HMOs should submit no-payment bills. GHAA identified the following three options:

- Leave the responsibility for reporting no-payment bills with the hospitals and levy sanctions on those that fail to submit them and/or temporarily suspend their Medicare payments for fee-for-service patients.
- Return the responsibility for submitting no-payment bills to the HMOs and levy sanctions on those that do not comply.
- Adopt a new sampling strategy for the PROS that is not dependent on no-payment bills.

We did not recommend that the HMOs should be required to submit no-payment bills. Instead, we suggested that the HMOs should be responsible for submitting “comprehensive information about Medicare enrollees receiving inpatient hospital care” (see p. 37). In our opinion, identifying alternatives for processing no-payment bills is a moot issue. The questions that need to be addressed are: what are the minimum data the PROS need from each HMO to draw valid samples for reviewing inpatient care; what is the best source of those data; and what is the best way of making the data available to the PROS?

We believe that the minimum data necessary to ensure a valid random sample of inpatient care are a complete listing of all HMO enrollees who have been hospitalized during the period under review, the dates of hospitalization, and the medical condition treated. Concerning the source of the data, HMO regulations are explicit in requiring that HMOs create record-keeping systems that provide information about their enrollees. Consequently, we feel that HCFA must hold HMOs—not other organizations—responsible for providing the PROS with the information needed to carry out their review responsibilities.



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No where in this report does GAO discuss what criteria have been developed by the Health Care Financing Administration (HCFA) or the PROs for assessing risk contractors' internal QAPs, or in any way touch upon exactly how PROs evaluate the information they receive on internal QAPs. AMCRA believes the reason the report is silent on this issue is because the PROs have no methodically-developed criteria upon which to evaluate the effectiveness of QAPs and therefore have been unable to analyze the information compiled from risk contractors. How can GAO conclude that the internal QAPs are performing poorly when the PROs are basing their conclusions about QAPs on an inadequate understanding and knowledge of the data produced by QAPs? AMCRA believes this lack of expertise and competence on the part of PROs is at the heart of:

- (1) the reluctance of HCFA to mandate PRO review of QAPs,
- (2) the reluctance of Medicare risk contractors to voluntarily undergo QAP review by the PROs, and
- (3) the failure of PRO review of QAPs (limited review) to become the standard for assessing quality in Medicare risk contracts.

Therefore, AMCRA believes GAO's failure to explore this explanation is a significant flaw.

Aside from the fundamental problem described above, AMCRA has concerns over other general themes arising in this report.

The orientation of PROs is based on the structure of the fee-for-service environment. This method of record retrieval used by PROs has simply been layered onto managed care companies without due consideration of its applicability. Until PROs become oriented in their review approach to the structure of managed care entities, there will continue to be tension over record retrieval issues.



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unjustifiable that GAO did not examine the basic issue of whether the expense of the review program is balanced in comparison to the quality problems identified.

While AMCRA agrees, literally, with the statement included in the GAO report that, "After more than 3 years of operation, the PRO review program still has not provided the intended assurance...", we feel that it is the PRO's lack of methodological expertise and competence relative on assessing the quality of services provided under Medicare risk contracts and on assessing the effectiveness of the internal quality assurance plans (QAPs) that has lead to the failure of the PRO system. Sophisticated and effective quality assurance mechanisms exist within the managed care risk contractors' operations; it is the PROs' inability to responsibly and consistently evaluate those mechanisms (a fact that is repeated throughout the report) that is at the heart of the failure of the PRO review system to achieve what was intended. There has been a great deal of time, effort, and most importantly, taxpayers' dollars expended for reimbursement of PRO review of Medicare risk contractors. Likewise, managed care entities expend **significant** non-reimbursed resources engaging in compliance activities. The only palpable result has been the accumulation of a great deal of data for which no valid evaluative criteria has been established.

Therefore, it is the report's definition of the problem and recommended solutions with which AMCRA disagrees. The report suggests that the only possible reason for the failure of PRO review of managed care risk contractors is some inadequacy or failure on the part of the risk contractors' QAPs. In AMCRA's opinion, the solution is not to throw good money after bad by encouraging the PROs to continue "business as usual" in the review of managed care risk contractors. PROs must be required to learn more about the organizations they are reviewing, to modify their review procedures to adequately relate to the managed care world, and to develop defensible, applicable quality review criteria with which to evaluate the QAPs of Medicare risk contractors.

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has had over 12,000 records pulled by the PRO. Under these circumstances, it is unreasonable for the report to suggest that the PROs do not have enough data by which to evaluate quality. The only reasonable conclusion is that they are ill-equipped to process this data and have not been given definitive guidance from HSQB on how to go about such analysis.

The cause of the problem has not been the recalcitrance of the managed care risk contractors. The solution is not the granting of more hardball authority to PROs to force managed care companies into fee-for-service evaluative molds. The problem is that PROs do have the ability to assess the data that is generated by QAPs and therefore cannot adequately evaluate the effectiveness of those QAPs. The solution, therefore, is to develop a more sophisticated understanding of and orientation to managed care delivery mechanisms so appropriate evaluative criteria can be developed and applied.

Attached you will find specific, page-by-page comments on the GAO report. I hope these comments are valuable, and we stand ready to discuss them at your convenience.

Sincerely,

A handwritten signature in black ink that reads "Charles W. Stellar". The signature is written in a cursive, slightly slanted style.

Charles W. Stellar
Executive Vice President



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The purpose of a managed care delivery systems is to question the "status quo" in health care delivery; to evaluate the appropriateness of health care treatment suggested for patients in order to assure quality, coordination, and cost-effectiveness. Understanding that, it is counterproductive for PROs to steadfastly insist that managed care entities operate more like fee-for-service providers. Is the purpose of the PRO review system to force managed care entities into fee-for-service molds for the sake of familiarity, or is the purpose to build the understanding of this new method of delivering health care so that its quality can be evaluated appropriately while not unreasonably adding to the cost? If it is the latter, this report ignores its most important purpose.

See comment 1.

This report is also silent on the question of how the expenditure of resources both by the federal government and by managed care risk contractors relates to the actual level of complaints received from Medicare beneficiaries served in managed care settings. The report is replete with references to how managed care entities may make it more difficult for PROs to fulfill their contractual obligations to HCFA and therefore make it more difficult for PROs to be reimbursed. However, no where does the report indicate if the level of PRO review is reasonable in relation to the complaints of Medicare risk contract enrollees. Is the purpose to maintain the business interests of the PROs or to establish the most cost-effective quality assurance mechanism possible for the protection of Medicare beneficiaries?

See comment 2.

This report leaves the impression that there are no controls on risk contractors to safeguard possible under-serving the Medicare population. In fact, there are civil monetary penalties available by law, and there are appeals procedures available to beneficiaries who are dissatisfied with their health care services.

In summary, it is AMCRA's view that the report should have concluded that PRO review of Medicare risk contractors has failed because of a lack of guidance on technical evaluative issues from Health Standards Quality Bureau (HSQB), and the PRO's lack of expertise and analytical ability in relation to the QAPs. PROs have a costly review history that has resulted in the accumulation of literally thousands of case records. For example, one large AMCRA member

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Comments From the American Medical Peer Review Association



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January 18, 1991

Janet L. Shikles
Director for Health
Financing and Policy Issues
United States General
Accounting Office
Washington, D.C. 20543

Dear Ms. Shikles:

The American Medical Peer Review Association (AMPRA), representing Peer Review Organizations (PROs), appreciates the opportunity to comment on this General Accounting Office (GAO) report entitled, "MEDICARE: PRO Review Does Not Assure Quality of Care Provided by Risk HMOs". AMPRA strongly supports external review of HMOs/CMPs to assure that Medicare beneficiaries receive quality of care services. We applaud the work of the General Accounting Office in regard to this study and stand ready to work with the appropriate parties to develop a quality review program that can provide needed assurances to beneficiaries participating in Medicare risk HMOs. AMPRA believes that the report has accurately and thoroughly documented the present deficiencies in the external review system of Medicare HMO/CMP risk contractors.

GENERAL POLICY PRINCIPLES

AMPRA's response to GAO's report is in large measure guided by a set of fundamental principles that we as an Association have enunciated through the years. These principles can be stated as follows:

1. Medicare providers/practitioners should not only be required to have internal quality assurance systems in place to assure the potential or probable delivery of good quality of care (structure evaluation), providers/practitioners should be required to demonstrate the actual provision of good quality of care through a system of external peer review of individual case records (process and outcome evaluation);

The following are GAO's comments on AMCRA's letter dated January 22, 1991.

GAO Comments

1. AMCRA states that our report is silent on the question of whether the level of expenditure for PRO review of HMOs is justified relative to the number of Medicare enrollee complaints.

We agree with AMCRA's suggestion that it would be useful to make such a comparison. However, we could not do this because:

- HCFA's accounting system cannot identify that portion of the total PRO reimbursement that is for HMO review activities.
- As discussed on page 37, HCFA does not link the information from the PRO reviews with information in its computerized system for tracking enrollee complaints, nor does it maintain HMO-specific information.

2. AMCRA states that our report leaves the impression that there are no controls over HMOs to safeguard against underserving Medicare enrollees and, to dispel this impression, cites existing civil monetary penalties and appeals procedures.

We believe that AMCRA has interpreted correctly the main message of this report. In chapter 2, we conclude that HCFA does not have a true assessment of how effective most HMO QAPs are at identifying and correcting quality problems. In chapter 3, we conclude that the PRO external review program is not a safeguard against quality problems. Finally, our past work has identified weaknesses in HCFA's HMO oversight activities (see p. 13), and we have an ongoing study which suggests that not all of the problems have been corrected.

Appendix V
Comments From the American Medical Peer
Review Association

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General Accounting Office
January 18, 1991
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AMPRA appreciates the opportunity to comment of this report on Quality of Care in HMOs and looks forward to continued participation in the discussions to modify external review of prepaid health care.

Sincerely,



Andrew Webber
Executive Vice President

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General Accounting Office
January 18, 1991
Page Two

2. The most efficient, effective external peer review system is dependent on reviewer access to a uniform and comprehensive database of all patient encounters. Such a database permits external reviewers to analyze patient outcomes and aggregate provider/practitioner practice patterns and also permits the effective "targetting" of individual medical record review on identified concerns;
3. At the beginning of an external review program, providers/practitioners should all be subject to a consistent level and intensity of review oversight. Subsequent reductions in external review should be based on a demonstrated track record of providing good quality care as measured through external review results.

REPORT COMMENTS

AMPRA concurs with the major findings of this report and is supportive of legislative and administrative remedies to improve program effectiveness. To correct present program inefficiencies, AMPRA recommends adoption of the following:

Legislative Recommendations

1. Intermediate sanction authority for review organizations and HCFA for non-complying prepaid plans. Financial penalties and targeted provider exclusions should be options available short of plan termination.
2. HMOs, as a condition of participation, must assure the submission of a uniform inpatient encounter form ("no-pay" bill) to permit aggregate data analysis and effective case selection by external reviewers. We believe that the present mandate on hospitals to complete the inpatient encounter form is misplaced as evidenced by the spotty compliance to the HCFA requirement by the hospital industry.
3. The Department should develop and implement a strategy to require use of a uniform ambulatory encounter form in the HMO setting.

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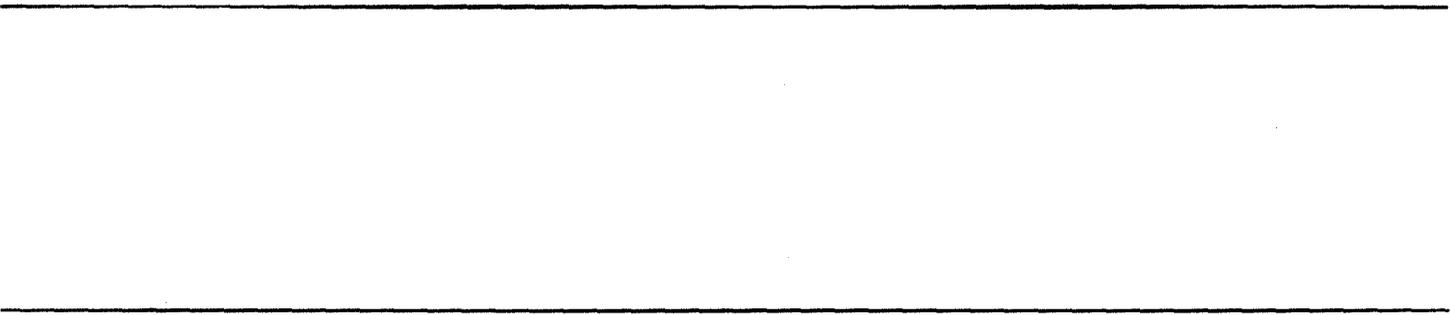
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Medicare: Reasonableness of Health Maintenance Organization Payments Not Assured (GAO/HRD-89-41, Mar. 7, 1989).

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